U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 3/28/23

Title: Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic (TRANSCEND)- St. Johns Community Health

Project Id: 0900f3eb820f2fcc

Accession #: NCHHSTP-PRT-1/30/23-a43fc

Project Contact: Carla Galindo

Organization: NCHHSTP/DHP/HRB/PRT

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 01/30/2023

Estimated Completion Date: 02/17/2023

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions *45 CFR 46.102(l)(4)*	3/14/23	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		3/16/23	Bonds_Constance (akj8) CTR OMB /PRA Coordinator

Description & Funding

Description

Priority:	Standard
Date Needed:	03/28/2023
Determination Start Date:	03/16/23
Description:	TRANSCEND is a 4-year non-research demonstration project that will be collecting quantitative and qualitative data for purposes of monitoring and evaluation. An OMB/PRA determination will be needed for data collection from funded recipients. In TRANSCEND, transgender-serving healthcare organizations (TG clinics) will collaborate with transgender-serving community-based organizations (TG CBOs) to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons. TG persons, especially transgender women (TGW), have a high lifetime risk of acquiring HIV. Black/African American (Black) and Hispanic/Latino (Hispanic) TGW have the highest prevalence of HIV among TG persons. Many TG persons experience poverty, homelessness, stigma, discrimination, and abuse; have mental health and substance use disorders; and need essential support services. Recipients provide comprehensive, co-located health services including HIV testing, preexposure prophylaxis (PrEP), gender-affirming hormone therapy, primary health care, and navigation. Navigation will be used to link TG persons as needed to services for mental health and substance use disorders and essential support services. Recipients will work with TG CBOs to engage TG persons in HIV testing and education and navigate them to TG clinics and other services. Program evaluation will be conducted using performance measures calculated from client-level, longitudinal data extracted from clinic electronic health records (EHR). These data will be linked to participant demographic information and sexual and injection drug behavioral history. Linkage will be performed by the recipient and participant data will be coded with a unique identifier to allow for longitudinal data analyses prior to data transmission to CDC every 6 months using a CDC-approved, secure virtual private network (VPN). Only the recipients will be able to link the unique identifier to the individual participants. Personally identifiable information (PII) will not be transmitted to CDC. Coded data will be transmitted to CDC every six months during the project period for CDC to analyze and calculate performance measures. All personally identifiable information (PII) will be removed by the recipients and the deidentified data files will be transferred to CDC using a secure FTP. All digital data will be stored on secure, password-protected servers and only project staff and authorized personnel will have access. Any paper documents will be stored in a locked cabinet that only required key staff will have access to. Key outcomes in the project include an increased number of TG persons who initiate, adhere to, and persist with PrEP; increased rates of viral suppression among TG persons with diagnosed HIV; and an increased number of TG persons with unmet needs who receive services for mental health and substance use disorders and other essential support services. Additional program evaluation will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and in the middle of the project period.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected

Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	TRANSCEND funds four TG clinics to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care. Navigation will also be used to link TG persons to services as needed for mental health and substance use disorder and other essential support services. These models will increase use of HIV prevention and treatment by TG persons to decrease HIV transmission and improve overall health and wellbeing.
Objective:	CDC will work in partnership with the four recipients to implement proven strategies for community-to-clinic integrated and holistic models to provide co-located services for TG persons. Status-neutral services include HIV testing, gender-affirming services including hormone therapy, STI testing and treatment, hepatitis testing and treatment, preventive health care, chronic disease care, mental health and substance use disorder services need assessments and linkage to services, and social service need assessment and linkage to services. These services will be developed with cultural and linguistic responsiveness for TG persons. This project has four strategies: (1) To provide integrated HIV testing, status-neutral HIV prevention and care services, and comprehensive TG health services to TG persons through TG CBO and clinic collaboratives; (2) To support use of mental health and substance use disorder services and other essential support services by TG persons with needs for these services; (3) To provide services that are culturally sensitive for TG persons, especially for Black and Hispanic persons; and (4) To support development of and participation in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide community-to-clinic, status-neutral, comprehensive services for TG persons. Objectives: To evaluate programs that provide community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons.
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Not Selected
SDOH Education:	Not Selected
SDOH Health Care Access:	Yes
SDOH Neighborhood and Environment:	Not Selected
SDOH Social and Community Context:	Not Selected
SDOH Indices:	TRANSCEND will identify TG client needs for essential support services (e.g., health insurance, housing, food assistance, child care, transportation, legal services, job training, employment assistance) to address social determinants of health.
Other SDOH Topics:	Not Selected

Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Programmatic Work
Target Populations to be Included/Represented:	American Indian or Alaska Native ; Asian ; Black or African American ; Hispanic or Latino ; Native Hawaiian or Other Pacific Islander ; White ; Transgender ; Adult 18-24 years ; Patient
Tags/Keywords:	Transgender women (TGW) ; Status neutral ; Ending the HIV Epidemic (EHE)
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will provide substantial technical assistance or oversight
Method Categories:	Individual Interviews (Qualitative); Other - Person-level longitudinal data collection via electronic health records
Methods:	The four recipients will focus their activities on transgender women, especially Black and Hispanic TGW, to achieve the greatest impact on HIV prevention and care and health equity for TG populations. All four recipients are in a Phase 1 of the Ending the HIV Epidemic in the U.S. (EHE) initiative jurisdiction. The approach for this demonstration project is to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for TG persons. Program evaluation will be conducted using client-level, longitudinal data extracted from the clinic#s EHR system with coded data, using a unique identifier that does not contain PII, transmitted to CDC every six months during the project period for calculation of performance measures. The performance measures will help guide ongoing quality improvement of clinic and CBO activities. Additional program evaluation and ongoing quality improvement will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and mid-project. Information from these surveys will be used by recipients to guide program development and quality improvement.
Collection of Info, Data or Biospecimen:	CDC will request coded person-level longitudinal data at baseline and every 6 months from each recipient, collected and stored through EHRs and then deidentified and transmitted to CDC. These data will allow CDC to calculate process and outcome measures to evaluate recipient performance and progress toward intended outcomes. CDC will request approval for an estimated 329 annual burden hours for the recipients to collect, enter or upload, and report client demographic and behavioral characteristics, client data from the EHR, and client surveys. There are no other costs to respondents other than their time. These data will be used to develop dashboards with calculated outcome measures that serve as feedback to programs to guide ongoing quality improvement activities. The dashboards will help ensure success by providing program effectiveness information that can be helpful to manage the project and ensure progress towards achieving intended outcomes. The information is also helpful to determine applicability of evidence-based approaches for different populations, settings, and contexts as a component of ongoing quality improvement. Extraction of data from EHR allows data collection to be efficient and timely. The data will be de-identified and comply with the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. For client demographic and behavioral information, the date of data collection will be included. For services provided by the TG clinic, TG CBO, or other entity or organization, the date of service will be included. Person-level longitudinal data will include demographic characteristics and self-reported sexual and injection drug use behaviors of clients and information about their encounters at TG clinics, TG CBOs, HIV clinics, and other clinics or organizations to understand TG persons enrolled in the project and linkage and receipt of services. These data will be linked at the person-level with health care data extracted from EHR in TG clinics and HIV clinics. All data linkages will be conducted by the TG clinic and de-identified data will be transmitted to CDC at least every 6 months to inform quality improvement activities. OMB/PRA approval will be requested. CDC will work with the recipients to participate in a national learning collaborative to share lessons learned and best practices for

Expected Use of Findings/Results and their impact:	TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons. Findings from the project and identified best practices will be shared with CDC colleagues, public health researchers, and other relevant individuals at CDC meetings and seminars and also will be presented at appropriate national conferences and published in peer reviewed public health journals.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	Yes, *see supporting info*

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic (TRANSCEND)	CDC-RFA-PS22-2209	2022	4	2000000.00

HSC Review

HSC Attributes

Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(l). The purpose of this activity is to implement proven	Yes

strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care. Navigation will also be used to link TG persons to services as needed for mental health and substance use disorder and other essential support services.

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects	
Do you anticipate this project will be exempt research or non-exempt research	

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
St. John's Well Child & Family Ctr	FWA00007207	05/23/22			

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Anne Kimball	05/09/2025		05/31/2025		Project Officer	opu7@cdc.gov	404-718-3642	PREVENTION RESEARCH TEAM
Carla Galindo	04/28/2023		12/08/2024	12/09/2024	Project Officer	fco4@cdc.gov	404-639-1902	PREVENTION RESEARCH TEAM
Dejene Marshall	02/17/2025				Project Officer	xht6@cdc.gov	404-639-8382	PREVENTION RESEARCH TEAM
Elena Fernandez	06/22/2024				Program Official	efernandez@wellchild.org	323-541-1600	St. John's Well Child & Family Ctr
Karen Hoover	10/17/2024	05/29/2022			Program Lead	ffw6@cdc.gov	404-639-8534	HIV RESEARCH BRANCH
Kashif Iqbal	12/09/2025				Project Officer	kai9@cdc.gov	404-718-8556	TREATMENT RESEARCH TEAM
Kazumi Yamaguchi	06/22/2024				Principal Investigator	kyamaguchi@wellchild.org	323-541-1600	St. John's Well Child & Family Ctr
					Project		404-	PREVENTION

Kessy Jean	02/14/2026				Coordinator	qvq2@cdc.gov	718-3836	RESEARCH TEAM
Sanon Williams	06/22/2024				Project Coordinator	req8@cdc.gov	404-498-4856	PROGRAM OPERATIONS TEAM
Tameka Webb	03/01/2026				Data Owner	vdo4@cdc.gov	404-213-5890	PREVENTION RESEARCH TEAM
Toyin Idehen	06/22/2024				Program Lead	tidehen@carecg.com	844-312-2273	St. John's Well Child & Family Ctr
Weiming Zhu	02/01/2026				Statistician	nje7@cdc.gov	404-718-5786	PREVENTION RESEARCH TEAM
Ya-lin Huang	12/13/2025				Statistician	kiq1@cdc.gov	404-639-2992	PREVENTION RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 6/30/23

Proposed Data Collection End Date: 6/29/26

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL: TBD

Data Use Contact: Anne Kimball

Public Access Justification: TRANSCEND prohibits recipients from submitting any personally identifying information (PII) to CDC. PII includes any information that can be used to distinguish or trace an individual#s identity, such as name, social security number, date and place of birth, mother#s maiden name, or biometric records. Each grantee is responsible for de-identifying all client-level data using a coded unique identifier prior to submitting client-level data to CDC. There are no confidentiality concerns for the data CDC receives.

How Access Will Be Provided for Data:	Based on an initial determination, the TRANSCEND data managed by CDC can be made publicly accessible. A data use agreement (DUA) will be in place. After all data are collected, CDC will make a final determination based on several factors including, but not limited to, data quality and utility. CDC will update this protocol based on its final determination for accessibility of the TRANSCEND data.
Plans for Archival and Long Term Preservation:	CDC protects sensitive data, of all formats, through administrative, technical, and physical security safeguards which guard against risks such as loss, unauthorized access or use, destruction, modification, or unintended or inappropriate disclosure. Different methods of security include encryption and/or password protection. Data will be only accessible by project staff and access will only be granted to those who follow appropriate data security and confidentiality guidelines. At a future date, CDC will develop a Records Management Plan for this project. TRANSCEND datasets will be collected from individual Secure FTP sites and stored in a password-protected CDC shared folder. Datasets will be archived for long-term retention.

Spatiality

Country	State/Province	County/Region
United States	California	Los Angeles County

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	Galindo_Carla (fco4) Project Contact	03/02/2023	Attached is the TRANSCEND Satisfaction Survey.	Data Collection Form	TRANSCEND Client Satisfaction Survey_02.10.23_PD LJF_CAG_02.21.23_Clean.docx

Current	Galindo_Carla (fco4) Project Contact	03/02/2023	Attached is the TRANSCEND Data Use Agreement.	Data Use Agreement	TRANSCEND_Data_Use_Plan_2.28.2023_clean.docx
Current	Galindo_Carla (fco4) Project Contact	03/02/2023	Attached is the Data Variables document with variables that we will collect from clinic electronica health records.	Data Collection Form	Data Variables_2.27.23.docx
Current	Galindo_Carla (fco4) Project Contact	03/02/2023	Attached is the TRANSCEND Intake Form.	Data Collection Form	TRANSCEND Intake Form_021023_PD LJF_KI_clean final.docx
Current	Galindo_Carla (fco4) Project Contact	03/02/2023	Attached is St. Johns TRANSCEND Protocol.	Protocol	St. Johns - TRANSCEND Protocol 03.01.23_Final STARS.docx

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 3/27/23

Title: Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic (TRANSCEND) - Callen-Lorde

Project Id: 0900f3eb820ec944

Accession #: NCHHSTP-PRT-2/28/23-d4a8c

Project Contact: Dejene M Marshall

Organization: NCHHSTP/DHP/HRB/PRT

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 06/30/2022

Estimated Completion Date: 06/29/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of	3/13/23	Dodson_Janella R. (jhd7) CIO HSC

	research as defined in 46.102(l). The purpose of this activity is to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care.		
PRA: **PRA Applies**		3/13/23	Bonds_Constance (akj8) CTR OMB /PRA Coordinator

Description & Funding

Description

Priority: Standard

Date Needed: 03/23/2023

Determination Start Date: 03/13/23

Description: TRANSCEND is a 4-year non-research demonstration project that will be collecting quantitative and qualitative data for purposes of monitoring and evaluation. An OMB/PRA determination will be needed for data collection from funded recipients. In TRANSCEND, transgender-serving healthcare organizations (TG clinics) will collaborate with transgender-serving community-based organizations (TG CBOs) to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons. TG persons, especially transgender women (TGW), have a high lifetime risk of acquiring HIV. Black/African American (Black) and Hispanic/Latino (Hispanic) TGW have the highest prevalence of HIV among TG persons. Many TG persons experience poverty, homelessness, stigma, discrimination, and abuse; have mental health and substance use disorders; and need essential support services. Recipients provide comprehensive, co-located health services including HIV testing, preexposure prophylaxis (PrEP), gender-affirming hormone therapy, primary health care, and navigation. Navigation will be used to link TG persons as needed to services for mental health and substance use disorders and essential support services. Recipients will work with TG CBOs to engage TG persons in HIV testing and education and navigate them to TG clinics and other services. Program evaluation will be conducted using performance measures calculated from client-level, longitudinal data extracted from clinic electronic health records (EHR). These data will be linked to participant demographic information and sexual and injection drug behavioral history. Linkage will be performed by the recipient and participant data will be coded with a unique identifier to allow for longitudinal analyses prior to data transmission to CDC every 6 months using a CDC-approved, secure virtual private network (VPN). Only the recipients will be able to link the unique identifier to the individual participants. Personally identifiable information (PII) will not be transmitted to CDC. Deidentified Coded data will be transmitted to CDC every six months during the project period for CDC to analyze and calculate performance measures. All personally identifiable information will be removed by the recipients and the deidentified data files will be transferred to CDC using a secure FTP. All digital data will be stored on secure, password-protected servers and only project staff and authorized personnel will have access. Any paper documents will be stored in a locked cabinet that only required key staff will have access to. Key outcomes in the project include an increased number of TG persons who initiate, adhere to, and persist with PrEP; increased rates of viral suppression among TG persons with diagnosed HIV; and an increased number of TG persons with unmet needs who receive services for mental health and substance use disorders and other essential support services. Additional program evaluation will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and in the middle of the project period.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	TRANSCEND funds four TG clinics to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care. Navigation will also be used to link TG persons to services as needed for mental health and substance use disorder and other essential support services. These models will increase use of HIV prevention and treatment by TG persons to decrease HIV transmission and improve overall health and well-being.
Objective:	CDC will work in partnership with the four recipients to develop community-to-clinic integrated and holistic models to provide co-located services for TG persons. Status-neutral services include HIV testing, gender-affirming services including hormone therapy, STI testing and treatment, hepatitis testing and treatment, preventive health care, chronic disease care, mental health and substance use disorder services need assessments and linkage to services, and social service need assessment and linkage to services. These services will be developed with cultural and linguistic responsiveness for TG persons. This project has four strategies: (1) To provide integrated HIV testing, status-neutral HIV prevention and care services, and comprehensive TG health services to TG persons through TG CBO and clinic collaboratives; (2) To support use of mental health and substance use disorder services and other essential support services by TG persons with needs for these services; (3) To provide services that are culturally sensitive for TG persons, especially for Black and Hispanic persons; and (4) To support development of and participation in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide community-to-clinic, status-neutral, comprehensive services for TG persons. Objective: To evaluate programs that provide community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Yes
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Not Selected
SDOH Education:	Not Selected
SDOH Health Care Access:	Yes

SDOH Neighborhood and Environment:	Not Selected
SDOH Social and Community Context:	Not Selected
SDOH Indices:	TRANSCEND will identify TG client needs for essential support services (e.g., health insurance, housing, food assistance, child care, transportation, legal services, job training, employment assistance) to address social determinants of health.
Other SDOH Topics:	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Programmatic Work
Target Populations to be Included/Represented:	American Indian or Alaska Native ; Asian ; Black or African American ; Hispanic or Latino ; Native Hawaiian or Other Pacific Islander ; White ; Transgender ; Adult 18-24 years ; Patient
Tags/Keywords:	Transgender women (TGW) ; status neutral ; End the HIV Epidemic (EHE)
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will provide substantial technical assistance or oversight
Method Categories:	Individual Interviews (Qualitative); Other - Person-level longitudinal data collection via electronic health records
Methods:	The four recipients will focus their activities on transgender women, especially Black and Hispanic TGW, to achieve the greatest impact on HIV prevention and care and health equity for TG populations. All four recipients are in a Phase 1 of the Ending the HIV Epidemic in the U.S. (EHE) initiative jurisdiction. The approach for this demonstration project is to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for TG persons. Program evaluation will be conducted using client-level, longitudinal data extracted from the clinic#s EHR system with coded data, using a unique identifier that does not contain PII, transmitted to CDC every six months during the project period for calculation of performance measures. The performance measures will help guide ongoing quality improvement of clinic and CBO activities. Additional program evaluation and ongoing quality improvement will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and mid-project. Information from these surveys will be used by recipients to guide program development and quality improvement.
Collection of Info, Data or Biospecimen:	CDC will request coded person-level longitudinal data at baseline and every 6 months from each recipient, collected and stored through EHRs and then deidentified and transmitted to CDC. These data will allow CDC to calculate process and outcome measures to evaluate recipient performance and progress toward intended outcomes. CDC will request approval for an estimated 329 annual burden hours for the recipients to collect, enter or upload, and report client demographic and behavioral characteristics, client data from the EHR, and client surveys. There are no other costs to respondents other than their time. These data will be used to develop dashboards with calculated outcome measures that serve as feedback to programs to guide ongoing quality improvement activities. The dashboards will help ensure success by providing program effectiveness information that can be helpful to manage the project and ensure progress towards achieving intended outcomes. The information is also helpful to determine applicability of evidence-based approaches for different populations, settings, and contexts as a component of ongoing quality improvement. Extraction of data from EHR allows data collection to be efficient and timely. The data will be de-identified and comply with the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. For client demographic and behavioral information, the date of data collection will be included. For services

	provided by the TG clinic, TG CBO, or other entity or organization, the date of service will be included. Person-level longitudinal data will include demographic characteristics and self-reported sexual and injection drug use behaviors of clients and information about their encounters at TG clinics, TG CBOs, HIV clinics, and other clinics or organizations to understand TG persons enrolled in the project and linkage and receipt of services. These data will be linked at the person-level with health care data extracted from EHR in TG clinics and HIV clinics. All data linkages will be conducted by the TG clinic and de-identified data will be transmitted to CDC at least every 6 months to inform quality improvement activities. OMB/PRA approval will be requested.
Expected Use of Findings/Results and their impact:	CDC will work with the recipients to participate in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons. Findings from the project and identified best practices will be shared with CDC colleagues, public health researchers, and other relevant individuals at CDC meetings and seminars and also will be presented at appropriate national conferences and published in peer reviewed public health journals.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	No
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	Yes, *see supporting info*

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic (TRANSCEND)	CDC-RFA-PS22-2209	2022	4	2000000.00

HSC Review

HSC Attributes

Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(l). The purpose of this activity is to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care.	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects	
Do you anticipate this project will be exempt research or non-exempt research	

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection

Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Callen-Lorde					CDC-RFA-PS22-2209

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Ali Harris	n/a	n/a	n/a	n/a	Technical Monitor	aharris@callen-lorde.org	212-271-7200	Callen-Lorde
Anne Kimball	05/09/2025		05/31/2025		Project Officer	opu7@cdc.gov	404-718-3642	PREVENTION RESEARCH TEAM
Asa Radix	06/22/2024				Principal Investigator	aradix@callen-lorde.org	212-271-7200	Callen-Lorde
Ashwini Hardikar	06/22/2024				Program Lead	ahardikar@callen-lorde.org	212-271-7200	Callen-Lorde
Carla Galindo	04/28/2023		12/08/2024	12/09/2024	Project Officer	fco4@cdc.gov	404-639-1902	PREVENTION RESEARCH TEAM
Dejene Marshall	n/a	n/a	n/a	n/a	Project Officer	xht6@cdc.gov	404-639-8382	PREVENTION RESEARCH TEAM
Karen Hoover	n/a	n/a	n/a	n/a	Program Lead	ffw6@cdc.gov	404-639-8534	HIV RESEARCH BRANCH
Kashif Iqbal	12/09/2025				Project Officer	kai9@cdc.gov	404-718-8556	TREATMENT RESEARCH TEAM

Perri Hawley	06/22/2024				Technical Monitor	phawley@callen-lorde.org	212-271-7200	Callen-Lorde
Sanon Williams	06/22/2024				Project Coordinator	req8@cdc.gov	404-498-4856	PROGRAM OPERATIONS TEAM
Tameka Webb	03/01/2026				Data Owner	vdo4@cdc.gov	404-213-5890	PREVENTION RESEARCH TEAM
Weiming Zhu	02/01/2026				Statistician	nje7@cdc.gov	404-718-5786	PREVENTION RESEARCH TEAM
Ya-lin Huang	12/13/2025				Statistician	kiq1@cdc.gov	404-639-2992	PREVENTION RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 6/30/23

Proposed Data Collection End Date: 6/29/26

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL: To be determined

Data Use Contact: Anne Kimball

Public Access Justification: TRANSCEND prohibits recipients from submitting any personally identifying information (PII) to CDC. PII includes any information that can be used to distinguish or trace an individual#s identity, such as name, social security number, date and place of birth, mother#s maiden name, or biometric records. Each grantee is responsible for de-identifying all client-level data using a coded unique identifier prior to submitting client-level data to CDC. There are no confidentiality concerns for the data CDC receives.

How Access Will Be Provided for Data: Based on an initial determination, the TRANSCEND data managed by CDC can be made publicly accessible. A data use agreement (DUA) will be in place. After all data are collected, CDC will make a final determination based on several factors including, but not limited to, data quality and utility. CDC will update this protocol based on its final determination for accessibility of the TRANSCEND data.

CDC protects sensitive data, of all formats, through administrative, technical, and physical security safeguards which guard against

Plans for Archival and Long Term Preservation:

risks such as loss, unauthorized access or use, destruction, modification, or unintended or inappropriate disclosure. Different methods of security include encryption and/or password protection. Data will be only accessible by project staff and access will only be granted to those who follow appropriate data security and confidentiality guidelines. At a future date, CDC will develop a Records Management Plan for this project. TRANSCEND datasets will be collected from individual Secure FTP sites and stored in a password-protected CDC shared folder. Datasets will be archived for long-term retention.

Spatiality

Country	State/Province	County/Region
United States	New York	New York County

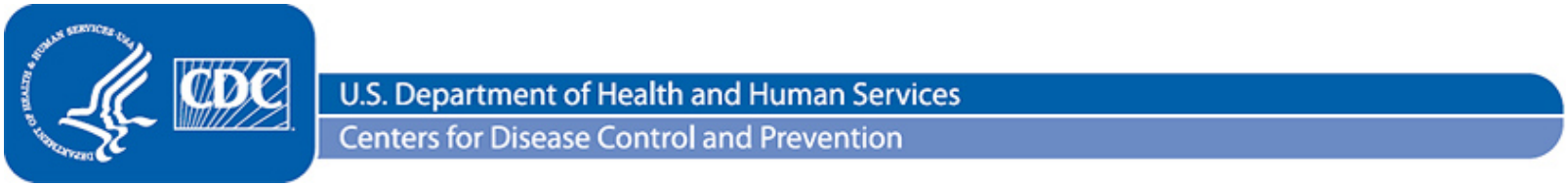
Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	Marshall_Dejene (xht6) Project Contact	03/02/2023	Intake Form - TRANSCEND	Data Collection Form	TRANSCEND Intake Form_021023_PD LJF_KI_clean final.docx
Current	Marshall_Dejene (xht6) Project Contact	03/02/2023	Client Satisfaction Survey - TRANSCEND	Data Collection Form	TRANSCEND Client Satisfaction Survey_02.10.23_PD LJF_CAG_02.21.23_Clean.docx
	Marshall_Dejene				

Current	(xht6) Project Contact	03/02/2023	Data Variables List - TRANSCEND	Data Collection Form	Data Variables_2.27.23.docx
Current	Marshall_Dejene (xht6) Project Contact	03/02/2023	Data Use Agreement - TRANSCEND	Non Disclosure Agreement	TRANSCEND_Data_Use_Plan_2.28.2023_clean.docx
Current	Marshall_Dejene (xht6) Project Contact	03/02/2023	Protocol - Callen-Lorde TRANSCEND	Data Collection Form	Callen-Lorde TRANSCEND Protocol - Clean 3.1.23.docx



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 3/28/23

Title:	Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic (TRANSCEND)-WWH
Project Id:	0900f3eb820ec945
Accession #:	NCHHSTP-TRT-2/27/23-d3331
Project Contact:	Kashif Iqbal
Organization:	NCHHSTP/DHP/HRB/TRT
Status:	**Pending Regulatory Clearance**
Intended Use:	**Project Determination**
Estimated Start Date:	06/30/2022
Estimated Completion Date:	06/29/2026
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	CDC-2022-0128

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of	3/13/23	Dodson_Janella R. (jhd7) CIO HSC

	research as defined in 46.102(l). The purpose of this activity is to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care.		
PRA: **PRA Applies**		3/13/23	Bonds_Constance (akj8) CTR OMB /PRA Coordinator

Description & Funding

Description

Priority: Standard

Date Needed: 03/23/2023

Determination Start Date: 03/13/23

Description: TRANSCEND is a 4-year non-research demonstration project that will be collecting quantitative and qualitative data for purposes of monitoring and evaluation. An OMB/PRA determination will be needed for data collection from funded recipients. In TRANSCEND, transgender-serving healthcare organizations (TG clinics) will collaborate with transgender-serving community-based organizations (TG CBOs) to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons. TG persons, especially transgender women (TGW), have a high lifetime risk of acquiring HIV. Black/African American (Black) and Hispanic/Latino (Hispanic) TGW have the highest prevalence of HIV among TG persons. Many TG persons experience poverty, homelessness, stigma, discrimination, and abuse; have mental health and substance use disorders; and need essential support services. Recipients provide comprehensive, co-located health services including HIV testing, preexposure prophylaxis (PrEP), gender-affirming hormone therapy, primary health care, and navigation. Navigation will be used to link TG persons as needed to services for mental health and substance use disorders and essential support services. Recipients will work with TG CBOs to engage TG persons in HIV testing and education and navigate them to TG clinics and other services. Program evaluation will be conducted using performance measures calculated from client-level, longitudinal data extracted from clinic electronic health records (EHR). These data will be linked to participant demographic information and sexual and injection drug behavioral history. Linkage will be performed by the recipient and participant data will be coded with a unique identifier to allow for longitudinal analyses prior to data transmission to CDC every 6 months using a CDC-approved, secure virtual private network (VPN). Only the recipients will be able to link the unique identifier to the individual participants. Personally identifiable information (PII) will not be transmitted to CDC. Coded data will be transmitted to CDC every six months during the project period for CDC to analyze and calculate performance measures. All personally identifiable information will be removed by the recipients and the deidentified data files will be transferred to CDC using a secure FTP. All digital data will be stored on secure, password-protected servers and only project staff and authorized personnel will have access. Any paper documents will be stored in a locked cabinet that only required key staff will have access to. Key outcomes in the project include an increased number of TG persons who initiate, adhere to, and persist with PrEP; increased rates of viral suppression among TG persons with diagnosed HIV; and an increased number of TG persons with unmet needs who receive services for mental health and substance use disorders and other essential support services. Additional program evaluation will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and in the middle of the project period.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	TRANSCEND funds four TG clinics to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care. Navigation will also be used to link TG persons to services as needed for mental health and substance use disorder and other essential support services. These models will increase use of HIV prevention and treatment by TG persons to decrease HIV transmission and improve overall health and well-being.
Objective:	CDC will work in partnership with the four recipients to implement proven strategies for community-to-clinic integrated and holistic models to provide co-located services for TG persons. Status-neutral services include HIV testing, gender-affirming services including hormone therapy, STI testing and treatment, hepatitis testing and treatment, preventive health care, chronic disease care, mental health and substance use disorder services need assessments and linkage to services, and social service need assessment and linkage to services. These services will be developed with cultural and linguistic responsiveness for TG persons. This project has four strategies: (1) To provide integrated HIV testing, status-neutral HIV prevention and care services, and comprehensive TG health services to TG persons through TG CBO and clinic collaboratives; (2) To support use of mental health and substance use disorder services and other essential support services by TG persons with needs for these services; (3) To provide services that are culturally sensitive for TG persons, especially for Black and Hispanic persons; and (4) To support development of and participation in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide community-to-clinic, status-neutral, comprehensive services for TG persons. Attached is the protocol for Whitman-Walker Health (WWH) located in Washington DC. Objectives: To evaluate programs that provide community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Yes
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Not Selected
SDOH Education:	Not Selected
SDOH Health Care Access:	Yes

SDOH Neighborhood and Environment:	Not Selected
SDOH Social and Community Context:	Not Selected
SDOH Indices:	TRANSCEND will identify TG client needs for essential support services (e.g., health insurance, housing, food assistance, childcare, transportation, legal services, job training, employment assistance) to address social determinants of health.
Other SDOH Topics:	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Programmatic Work
Target Populations to be Included/Represented:	American Indian or Alaska Native ; Asian ; Black or African American ; Hispanic or Latino ; Native Hawaiian or Other Pacific Islander ; White ; Transgender ; Adult 18-24 years ; Patient
Tags/Keywords:	Health Services for Transgender Persons
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will provide substantial technical assistance or oversight
Method Categories:	Individual Interviews (Qualitative); Other - Person-level longitudinal data collection via electronic health records
Methods:	The four recipients will focus their activities on transgender women, especially Black and Hispanic TGW, to achieve the greatest impact on HIV prevention and care and health equity for TG populations. All four recipients are in a Phase 1 of the Ending the HIV Epidemic in the U.S. (EHE) initiative jurisdiction. The approach for this demonstration project is to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for TG persons. Program evaluation will be conducted using client-level, longitudinal data extracted from the clinic#s EHR system with coded data, using a unique identifier that does not contain PII, transmitted to CDC every six months during the project period for calculation of performance measures. The performance measures will help guide ongoing quality improvement of clinic and CBO activities. Additional program evaluation and ongoing quality improvement will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and mid-project. Information from these surveys will be used by recipients to guide program development and quality improvement.
Collection of Info, Data or Biospecimen:	CDC will request coded person-level longitudinal data at baseline and every 6 months from each recipient, collected and stored through EHRs and then deidentified and transmitted to CDC. These data will allow CDC to calculate process and outcome measures to evaluate recipient performance and progress toward intended outcomes. CDC will request approval for an estimated 329 annual burden hours for the recipients to collect, enter or upload, and report client demographic and behavioral characteristics, client data from the EHR, and client surveys. There are no other costs to respondents other than their time. These data will be used to develop dashboards with calculated outcome measures that serve as feedback to programs to guide ongoing quality improvement activities. The dashboards will help ensure success by providing program effectiveness information that can be helpful to manage the project and ensure progress towards achieving intended outcomes. The information is also helpful to determine applicability of evidence-based approaches for different populations, settings, and contexts as a component of ongoing quality improvement. Extraction of data from EHR allows data collection to be efficient and timely. The data will be de-identified and comply with the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and

	Tuberculosis Programs. For client demographic and behavioral information, the date of data collection will be included. For services provided by the TG clinic, TG CBO, or other entity or organization, the date of service will be included. Person-level longitudinal data will include demographic characteristics and self-reported sexual and injection drug use behaviors of clients and information about their encounters at TG clinics, TG CBOs, HIV clinics, and other clinics or organizations to understand TG persons enrolled in the project and linkage and receipt of services. These data will be linked at the person-level with health care data extracted from EHR in TG clinics and HIV clinics. All data linkages will be conducted by the TG clinic and de-identified data will be transmitted to CDC at least every 6 months to inform quality improvement activities. OMB/PRA approval will be requested.
Expected Use of Findings/Results and their impact:	CDC will work with the recipients to participate in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons. Findings from the project and identified best practices will be shared with CDC colleagues, public health researchers, and other relevant individuals at CDC meetings and seminars and will be presented at appropriate national conferences and published in peer reviewed public health journals.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	Yes, *see supporting info*

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic	CDC-RFA-PS22-2209	2022	4	2000000.00

HSC Review

HSC Attributes

Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(l). The purpose of this activity is to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care.	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects	
Do you anticipate this project will be exempt research or non-exempt research	

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection

Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Whitman-Walker Clinic d/b/a Whitman-Walker Health	FWA00000156	10/16/24			CDC-RFA-PS22-2209

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Amie Amie Krautwurst	n/a	n/a	n/a	n/a	Program Official	akrautwurst@whitman-walker.org		Whitman-Walker Clinic d/b/a Whitman-Walker Health
Anne Kimball	05/09/2025		05/31/2025		Project Officer	opu7@cdc.gov	404-718-3642	PREVENTION RESEARCH TEAM
britt walsh	02/01/2026				Principal Investigator	bwalsh@whitman-walker.org	202-797-4457	Whitman-Walker Clinic d/b/a Whitman-Walker Health
Carla Galindo	04/28/2023		12/08/2024	12/09/2024	Project Officer	fco4@cdc.gov	404-639-1902	PREVENTION RESEARCH TEAM
Dejene Marshall	n/a	n/a	n/a	n/a	Project Officer	xht6@cdc.gov	404-639-8382	PREVENTION RESEARCH TEAM
Karen Hoover	10/17/2024	05/29/2022			Program Lead	ffw6@cdc.gov	404-639-8534	HIV RESEARCH BRANCH

Kashif Iqbal	12/09 /2025				Project Officer	kai9@cdc.gov	404-718-8556	TREATMENT RESEARCH TEAM
Kessy Jean	02/14 /2026				Project Coordinator	qvq2@cdc.gov	404-718-3836	PREVENTION RESEARCH TEAM
Rachel McLaughlin	02/01 /2026				Program Official	rmclaughlin@whitman-walker.org		Whitman-Walker Clinic d/b/a Whitman-Walker Health
Sanon Williams	06/22 /2024				Project Coordinator	req8@cdc.gov	404-498-4856	PROGRAM OPERATIONS TEAM
Tameka Webb	03/01 /2026				Data Owner	vdo4@cdc.gov	404-213-5890	PREVENTION RESEARCH TEAM
Weiming Zhu	02/01 /2026				Statistician	nje7@cdc.gov	404-718-5786	PREVENTION RESEARCH TEAM
Ya-lin Huang	12/13 /2025				Statistician	kiq1@cdc.gov	404-639-2992	PREVENTION RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 6/30/23

Proposed Data Collection End Date: 6/29/26

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact: Anne Kimball

Public Access Justification:	TRANSCEND prohibits recipients from submitting any personally identifying information (PII) to CDC. PII includes any information that can be used to distinguish or trace an individual#s identity, such as name, social security number, date and place of birth, mother#s maiden name, or biometric records. Each grantee is responsible for de-identifying all client-level data using a coded unique identifier prior to submitting client-level data to CDC. There are no confidentiality concerns for the data CDC receives.
How Access Will Be Provided for Data:	Based on an initial determination, the TRANSCEND data managed by CDC can be made publicly accessible. A data use agreement (DUA) will be in place. After all data are collected, CDC will make a final determination based on several factors including, but not limited to, data quality and utility. CDC will update this protocol based on its final determination for accessibility of the TRANSCEND data.
Plans for Archival and Long Term Preservation:	CDC protects sensitive data, of all formats, through administrative, technical, and physical security safeguards which guard against risks such as loss, unauthorized access or use, destruction, modification, or unintended or inappropriate disclosure. Different methods of security include encryption and/or password protection. Data will be only accessible by project staff and access will only be granted to those who follow appropriate data security and confidentiality guidelines. At a future date, CDC will develop a Records Management Plan for this project. TRANSCEND datasets will be collected from individual Secure FTP sites and stored in a password-protected CDC shared folder. Datasets will be archived for long-term retention.

Spatiality

Country	State/Province	County/Region
United States	District of Columbia	

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info

Current	Iqbal_Kashif (kai9) Project Contact	03/02/2023	TRANSCEND client satisfaction survey	Data Collection Form	TRANSCEND Client Satisfaction Survey_02.10.23_PD LJF_CAG_02.21.23_Clean.docx
Current	Iqbal_Kashif (kai9) Project Contact	03/02/2023	WWH protocol	Protocol	CDC_TRANSCEND Protocol WWH_revised_KI_clean ACS.docx
Current	Iqbal_Kashif (kai9) Project Contact	03/02/2023	data use plan	Non Disclosure Agreement	TRANSCEND_Data_Use_Plan_2.28.2023_clean.docx
Current	Iqbal_Kashif (kai9) Project Contact	03/02/2023	Data variable list	Data Collection Form	Data Variables_2.27.23.docx
Current	Iqbal_Kashif (kai9) Project Contact	03/02/2023	TRANSCEND intake form	Data Collection Form	TRANSCEND Intake Form_021023_PD LJF_KI_clean final.docx

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 3/28/23

Title: Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic (TRANSCEND) - Care Resource

Project Id: 0900f3eb820ec942

Accession #: NCHHSTP-PRT-2/28/23-d48d7

Project Contact: Anne Kimball

Organization: NCHHSTP/DHP/HRB/PRT

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 06/30/2022

Estimated Completion Date: 06/29/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: CDC-2022-0128

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(l). The purpose of this activity is to implement proven strategies for community-to-clinic integrated and holistic models to provide co-located services for TG persons.	3/10/23	Dodson_Janella R. (jhd7) CIO HSC

PRA: **PRA Applies**		3/13/23	Bonds_Constance (akj8) CTR OMB /PRA Coordinator

Description & Funding

Description

Priority: Standard

Date Needed: 03/23/2023

Determination Start Date: 03/13/23

Description: TRANSCEND is a 4-year non-research demonstration project that will be collecting quantitative and qualitative data for purposes of monitoring and evaluation. An OMB/PRA determination will be needed for data collection from funded recipients. In TRANSCEND, transgender-serving healthcare organizations (TG clinics) will collaborate with transgender-serving community-based organizations (TG CBOs) to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons. TG persons, especially transgender women (TGW), have a high lifetime risk of acquiring HIV. Black/African American (Black) and Hispanic/Latino (Hispanic) TGW have the highest prevalence of HIV among TG persons. Many TG persons experience poverty, homelessness, stigma, discrimination, and abuse; have mental health and substance use disorders; and need essential support services. Recipients provide comprehensive, co-located health services including HIV testing, preexposure prophylaxis (PrEP), gender-affirming hormone therapy, primary health care, and navigation. Navigation will be used to link TG persons as needed to services for mental health and substance use disorders and essential support services. Recipients will work with TG CBOs to engage TG persons in HIV testing and education and navigate them to TG clinics and other services. Program evaluation will be conducted using performance measures calculated from client-level, longitudinal data extracted from clinic electronic health records (EHR). These data will be linked to participant demographic information and sexual and injection drug behavioral history. Linkage will be performed by the recipient, and participant data will be coded with a unique identifier to allow for longitudinal analyses prior to data transmission to CDC every 6 months using a CDC-approved, secure virtual private network (VPN). Only the recipients will be able to link the unique identifier to the individual participants. Personally identifiable information (PII) will not be transmitted to CDC. Coded data will be transmitted to CDC every six months during the project period for CDC to analyze and calculate performance measures. All personally identifiable information will be removed by the recipients and the deidentified data files will be transferred to CDC using a secure FTP. All digital data will be stored on secure, password-protected servers and only project staff and authorized personnel will have access. Any paper documents will be stored in a locked cabinet that only required key staff will have access to. Key outcomes in the project include an increased number of TG persons who initiate, adhere to, and persist with PrEP; increased rates of viral suppression among TG persons with diagnosed HIV; and an increased number of TG persons with unmet needs who receive services for mental health and substance use disorders and other essential support services. Additional program evaluation will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and in the middle of the project period.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	TRANSCEND funds four TG clinics to partner with TG CBOs to implement proven strategies for community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care. Navigation will also be used to link TG persons to services as needed for mental health and substance use disorder and other essential support services. These models will increase use of HIV prevention and treatment by TG persons to decrease HIV transmission and improve overall health and wellbeing.
Objective:	CDC will work in partnership with the four recipients to implement proven strategies for community-to-clinic integrated and holistic models to provide co-located services for TG persons. Status-neutral services include HIV testing, gender-affirming services including hormone therapy, STI testing and treatment, hepatitis testing and treatment, preventive health care, chronic disease care, mental health and substance use disorder services need assessments and linkage to services, and social service need assessment and linkage to services. These services will be developed with cultural and linguistic responsiveness for TG persons. This project has four strategies: (1) To provide integrated HIV testing, status-neutral HIV prevention and care services, and comprehensive TG health services to TG persons through TG CBO and clinic collaboratives; (2) To support use of mental health and substance use disorder services and other essential support services by TG persons with needs for these services; (3) To provide services that are culturally sensitive for TG persons, especially for Black and Hispanic persons; and (4) To support development of and participation in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide community-to-clinic, status-neutral, comprehensive services for TG persons. Attached is the protocol for Care Resources Health Center located in Miami, FL. Objectives: To evaluate programs that provide community-to-clinic, status-neutral HIV prevention and care services for transgender (TG) persons.
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Yes
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Not Selected
SDOH Education:	Not Selected
SDOH Health Care Access:	Yes
SDOH Neighborhood and Environment:	Not Selected
SDOH Social and Community Context:	Not Selected

SDOH Indices:	TRANSCEND will identify TG client needs for essential support services (e.g., health insurance, housing, food assistance, child care, transportation, legal services, job training, employment assistance) to address social determinants of health.
Other SDOH Topics:	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens ; Programmatic Work
Target Populations to be Included/Represented:	American Indian or Alaska Native ; Asian ; Black or African American ; Hispanic or Latino ; Native Hawaiian or Other Pacific Islander ; White ; Transgender ; Adult 18-24 years ; Patient
Tags/Keywords:	Health Services for Transgender Persons ; HIV ; Status neutral services ; Ending the HIV Epidemic
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will provide substantial technical assistance or oversight
Method Categories:	Individual Interviews (Qualitative); Other - Collection of person-level longitudinal data via electronic health records
Methods:	The four recipients will focus their activities on transgender women, especially Black and Hispanic TGW, to achieve the greatest impact on HIV prevention and care and health equity for TG populations. All four recipients are in a Phase 1 of the Ending the HIV Epidemic in the U.S. (EHE) initiative jurisdiction. The approach for this demonstration project is to implement proven strategies for community-to-clinic, status-neutral HIV prevention and care services for TG persons. Program evaluation will be conducted using client-level, longitudinal data extracted from the clinic#s EHR system with coded data, using a unique identifier that does not contain PII, transmitted to CDC every six months during the project period for calculation of performance measures. The performance measures will help guide ongoing quality improvement of clinic and CBO activities. Additional program evaluation and ongoing quality improvement will be conducted through client surveys assessing clinic and CBO service provision, which will be administered at baseline and mid-project. Information from these surveys will be used by recipients to guide program development and quality improvement.
Collection of Info, Data or Biospecimen:	CDC will request coded person-level longitudinal data at baseline and every 6 months from each recipient, collected and stored through EHRs and then deidentified and transmitted to CDC. These data will allow CDC to calculate process and outcome measures to evaluate recipient performance and progress toward intended outcomes. CDC will request approval for an estimated 329 annual burden hours for the recipients to collect, enter or upload, and report client demographic and behavioral characteristics, client data from the EHR, and client surveys. There are no other costs to respondents other than their time. These data will be used to develop dashboards with calculated outcome measures that serve as feedback to programs to guide ongoing quality improvement activities. The dashboards will help ensure success by providing program effectiveness information that can be helpful to manage the project and ensure progress towards achieving intended outcomes. The information is also helpful to determine applicability of evidence-based approaches for different populations, settings, and contexts as a component of ongoing quality improvement. Extraction of data from EHR allows data collection to be efficient and timely. The data will be de-identified and comply with the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. For client demographic and behavioral information, the date of data collection will be included. For services provided by the TG clinic, TG CBO, or other entity or organization, the date of service will be included. Person-level longitudinal data will include demographic characteristics and self-reported sexual and injection drug use behaviors of clients and information about their encounters at TG clinics, TG CBOs, HIV clinics, and other clinics or organizations to understand TG persons enrolled in

	the project and linkage and receipt of services. These data will be linked at the person-level with health care data extracted from EHR in TG clinics and HIV clinics. All data linkages will be conducted by the TG clinic and de-identified data will be transmitted to CDC at least every 6 months to inform quality improvement activities. OMB/PRA approval will be requested.
Expected Use of Findings/Results and their impact:	CDC will work with the recipients to participate in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons. Findings from the project and identified best practices will be shared with CDC colleagues, public health researchers, and other relevant individuals at CDC meetings and seminars and also will be presented at appropriate national conferences and published in peer reviewed public health journals.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	Yes, *see supporting info*

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic	CDC-RFA-PS22-2209	2022	4	2000000.00

HSC Review

HSC Attributes

Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(l). The purpose of this activity is to implement proven strategies for community-to-clinic integrated and holistic models to provide co-located services for TG persons.	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects	
Do you anticipate this project will be exempt research or non-exempt research	

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Care Resource					CDC-RFA-PS22-2209

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Alicia Lee-Clarke	n/a	n/a	n/a	n/a	Co-Investigator	alee-clarke@careresource.org		Care Resource
Carla Galindo	04/28/2023		12/08/2024	12/09/2024	Project Officer	fco4@cdc.gov	404-639-1902	PREVENTION RESEARCH TEAM
Dejene Marshall	02/17/2025				Project Officer	xht6@cdc.gov	404-639-8382	PREVENTION RESEARCH TEAM
Douglas Steele	02/14/2026				Principal Investigator	dsteele@careresource.org		Care Resource
Karen Hoover	10/17/2024	05/29/2022			Program Lead	ffw6@cdc.gov	404-639-8534	HIV RESEARCH BRANCH
Kashif Iqbal	12/09/2025				Project Officer	kai9@cdc.gov	404-718-8556	TREATMENT RESEARCH TEAM
Kessy Jean	02/14/2026				Project Coordinator	qvq2@cdc.gov	404-718-3836	PREVENTION RESEARCH TEAM
Leimny Pineiro	02/14/2026				Project Coordinator	lpineiro@careresource.org		Care Resource

Myka Osorio	02/14/2026				Project Coordinator	mosorio@careresource.org		Care Resource
Sanon Williams	06/22/2024				Project Coordinator	req8@cdc.gov	404-498-4856	PROGRAM OPERATIONS TEAM
Tameka Webb	03/01/2026				Data Owner	vdo4@cdc.gov	404-213-5890	PREVENTION RESEARCH TEAM
Weiming Zhu	02/01/2026				Statistician	nje7@cdc.gov	404-718-5786	PREVENTION RESEARCH TEAM
Ya-lin Huang	12/13/2025				Statistician	kiq1@cdc.gov	404-639-2992	PREVENTION RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 6/30/23

Proposed Data Collection End Date: 6/29/26

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact: Anne Kimball

Public Access Justification: TRANSCEND prohibits recipients from submitting any personally identifying information (PII) to CDC. PII includes any information that can be used to distinguish or trace an individual#s identity, such as name, social security number, date and place of birth, mother#s maiden name, or biometric records. Each grantee is responsible for de-identifying all client-level data using a coded unique identifier prior to submitting client-level data to CDC. There are no confidentiality concerns for the data CDC receives.

Based on an initial determination, the TRANSCEND data managed by CDC can be made publicly accessible. A data use agreement (DUA) will be in place. After all data are collected, CDC will make a final determination based on several factors

How Access Will Be Provided for Data:

including, but not limited to, data quality and utility. CDC will update this protocol based on its final determination for accessibility of the TRANSCEND data.

Plans for Archival and Long Term Preservation:

CDC protects sensitive data, of all formats, through administrative, technical, and physical security safeguards which guard against risks such as loss, unauthorized access or use, destruction, modification, or unintended or inappropriate disclosure. Different methods of security include encryption and/or password protection. Data will be only accessible by project staff and access will only be granted to those who follow appropriate data security and confidentiality guidelines. At a future date, CDC will develop a Records Management Plan for this project. TRANSCEND datasets will be collected from individual Secure FTP sites and stored in a password-protected CDC shared folder. Datasets will be archived for long-term retention.

Spatiality

Country	State/Province	County/Region
United States	Florida	Miami-Dade County
United States	Florida	Broward County

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	Kimball_Anne (opu7) Project Contact	03/02/2023	Client intake form	Data Collection Form	TRANSCEND Intake Form_021023_PD LJF_KI_clean final.docx

Current	Kimball_Anne (opu7) Project Contact	03/02/2023	Survey	Data Collection Form	TRANSCEND Client Satisfaction Survey_02.10.23_PD LJF_CAG_02.21.23_Clean.docx
Current	Kimball_Anne (opu7) Project Contact	03/02/2023	Variable list	Data Collection Form	Data Variables_2.27.23.docx
Current	Kimball_Anne (opu7) Project Contact	03/02/2023	Data use plan	Non Disclosure Agreement	TRANSCEND_Data_Use_Plan_2.28.2023_clean.docx
Current	Kimball_Anne (opu7) Project Contact	03/02/2023	Protocol	Protocol	CDC TRANSCEND Protocol_CareResource_revised_AN_AK_clean.docx