HIV Prevention and Treatment Services among Young Men of Color who Have Sex with Men (YMSM of Color) and Young Transgender Persons of Color (YTG of Color) in the Deep South

Generic Information Collection Request under OMB #0920-1091

Section B: Supporting Statement

January 14, 2019

CONTACT

James W. Carey, PhD, MPH
Project Officer

Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
1600 Clifton Road, NE, Mailstop E-37
Atlanta, GA 30333
Phone: 404-639-1903

Fax: 404-639-1950
E-mail: jfc9@cdc.gov

TABLE OF CONTENTS

EXHIBITS

1. Respondent Universe and Sampling Methods

Site Selection

The study will be carried out in four cities located within four states: Atlanta, GA; New Orleans, Louisiana; Columbia, South Carolina; Miami/Ft. Lauderdale, Florida. These cities were selected, because they have high numbers of new HIV diagnoses among young MSM (YMSM) and young transgender (YTG) persons of color. These cities also have community-based organizations (CBOs) that are funded by CDC's existing PS17-1704 grant program to provide HIV prevention and care services to YMSM and YTG.

Georgia (Atlanta). Georgia ranked 2nd in the nation for highest rates of HIV cases in 2016 and 2015, and continued to have high rates of HIV diagnoses in 2014 at an estimated 28.2 per 100,000 population.[1] Atlanta, GA, which is located in Fulton and Dekalb counties, ranked among the top 10 counties in the United States with high rates of HIV diagnoses.[1] Someone Cares, Inc. was funded, under CDC's PS17-1704 grant program to provide HIV prevention and care services to YTG persons of color in New Orleans, Louisiana.

South Carolina (Columbia). South Carolina ranked 8th in the nation for highest rates of HIV cases in 2016 and 11th in 2015, and continued to have high rates of HIV diagnoses in 2014 at an estimated 18.7 per 100,000 population.[1] The South Carolina AIDS Council was funded under CDC's PS17-1704 grant program to provide HIV prevention and care services to YMSM of color in New Orleans, Louisiana.

Louisiana (New Orleans and Baton Rouge). Louisiana ranked 3rd in the nation for highest rates of HIV cases in 2016 and in 2015, and continued to have high rates of HIV diagnoses in 2014 at an estimated 31.5 per 100,000 population.[1] Crescent Cares was funded, under CDC's PS17-1704 grant program to provide HIV prevention and care services to YMSM of color in New Orleans, Louisiana.

Florida (Miami-Dade and Broward counties). Florida ranked 4th in the nation for highest rates of HIV cases in 2016 and in 2015, and continued to have high rates of HIV diagnoses in 2014 at an estimated 26.7 per 100,000 population.[1] Latinos Salud was funded, under CDC's PS17-1704 grant program to provide HIV prevention and care services to YMSM of color in New Orleans, Louisiana.

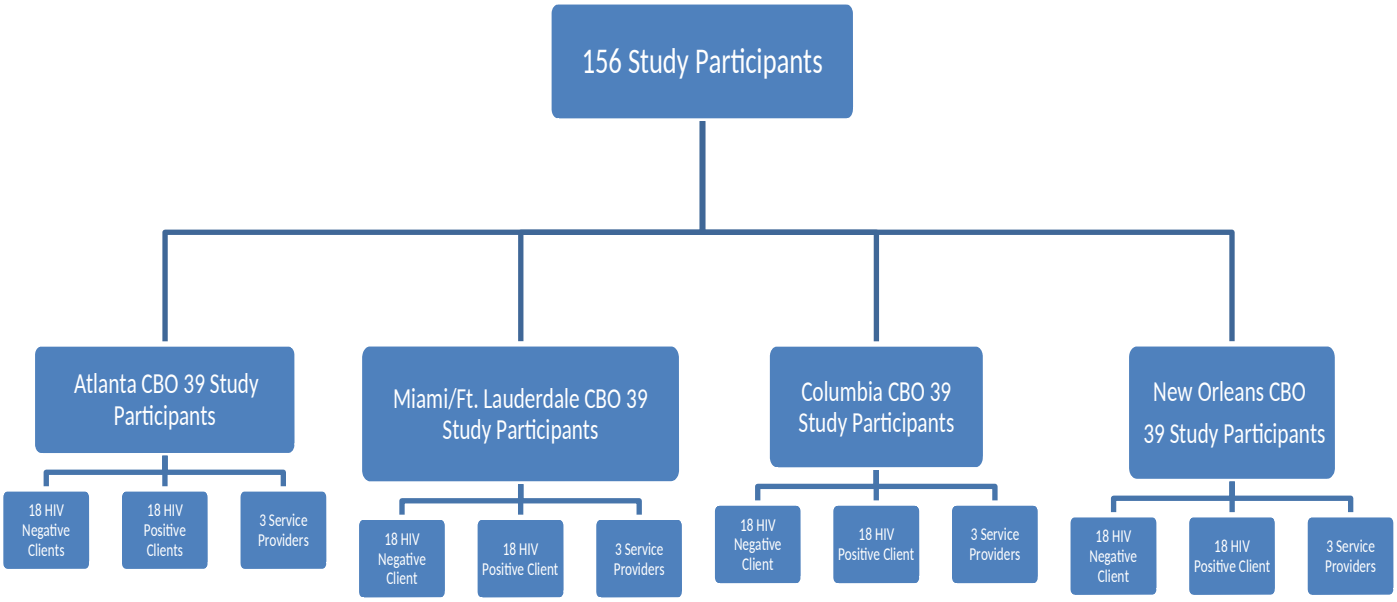
Target Population

The purpose of this information collection is to identify factors that influence how clients access and use HIV prevention, care, and treatment services offered at CBOs located in Deep South states. Specifically, this study focuses on CBO clients who are black/African American and Hispanic/Latino young men who have sex with men (YMSM) and young transgender youth (YTG). The study will take place in four CBOs located in Miami/Ft. Lauderdale, Florida;

Atlanta, Georgia; New Orleans/Baton Rouge, Louisiana; and Columbia, South Carolina. These four CBOs are funded by CDC's existing PS17-1704 grant program to provide HIV prevention and care services to YMSM and YTG.

Interview data will be gathered from a total of 156 persons. These include 144 black/African American and Hispanic/Latino YMSM and YTG, aged 18-24, who previously have received HIV prevention, care or treatment services from the four CBOs. In addition, we will gather interview data from 12 CBO staff involved with provision of services to YMSM and YTG clients. Study outcomes will be shared with local stakeholders and CBOs who may use the results implement site-specific improvements in their HIV prevention, care, or treatment services for YMSM and YTG.

Exhibit 1.1 Summary of Recruitment Targets



Inclusion criteria:

Deep South clients must be

- 18-24 years of age;
- able to speak English and consent to participate;
- Identify as a transgender person of color or man who has sex with men;
- Receive services at one of the identified community based organizations

Deep South service providers must be

- providing services to YMSM or YTG persons of color;
- able to speak English and consent to participate;

Exclusion criteria:

Deep South clients and service providers will be excluded from the study if they

- are unwilling or unable to provide consent;
- do not meet the other eligibility criteria.

This distribution of respondents may vary somewhat from place to place based on availability YMSM and YTG clients, as well as the numbers of eligible staff at the four CBOs. This is a qualitative research study and is not designed to make comparisons between groups or to make generalizations. Probability sampling methods are not appropriate for our qualitative study purposes. Instead we will select respondents to ensures a wide range of experiences or clients and staff are captured.

2. Procedures for the Collection of Information

To recruit CBO clients, program staff will post and give potential clients the Recruitment Flyer (**Attachment 1**). The flyers contain information on how a client can call the study contractor team if they are interested in participating in the study. The CBO program staff will never learn which of their clients called the contractor team, and likewise will never learn which clients were enrolled in the final client sample.

When a CBO client calls, a member of the contractor team will screen potential client participants for eligibility using a screening tool (**Attachment 3a**). If they are eligible, they will be invited to provide their contact information (name, phone, email), in order to schedule the in-depth interview. This contact information will be hand written on paper, and not be computerized on a form. When not in active use, the papers containing the contact information will be stored in locked cabinets separate from other study data at the contractor's office facility. These papers with the participant's contact information will be destroyed after the interview is completed and the interview data have been fully transcribed and verified for accuracy.

At the beginning of the in-depth interview, a member of the contractor team will review the purpose of the study with the participant and answer any questions they might have. The participant will be asked to provide signed informed consent (**Attachment 2**). This includes permission to audio record the interview. After the consent process is finished, the interview will begin.

To recruit the CBO service providers, the contractor will obtain a list of the personnel who are involved in providing HIV prevention and care services to PS17-1704 program participants from the CBO leads. Participation in this study will not impact PS17-1704 program personnel job performance, and there is no requirement to participate in this study as a function of job performance. Based on the names on this list, the contractor will invite CBO service providers to be interviewed, either face-to-face, or by phone. Service providers who choose to enroll in the study will be scheduled for an in-depth interview at a time and location that is convenient to them. Authorized contractor staff will confirm that participants are at least 18 years old during recruitment, but because participants will be selected from a pre-determined list, no additional screening will be required. At the time of the interview, staff will review the study procedures, after which participants will complete the informed consent and will receive a copy of the consent for their records (**Attachment 2**). CDC staff will not be involved with sample recruitment and will never know the identities of any study respondents.

For both the CBO client and the service providers, contractor staff will conduct qualitative, in-depth interviews lasting one hour, on average, to collect information for this study (**Attachments 3b-c**). Interviews will be conducted in a private setting by trained interviewers. With the respondent's permission, interviewers will digitally audio record each interview and will remind participants not to use their full names or other identifying information. Interviews will include a short, structured response section to collect participants' demographic information. The interviews will primarily include open-ended questions designed to elicit information on HIV prevention and care, and their perspectives on the PS17-1704 program in their jurisdiction.

Copies of the signed consent forms will be kept as required for possible IRB review for up to 10 years in a locked vault, located in the contractor's office facility. No data set file will contain any personally identifiable information from the participant; instead, a unique study ID number will be used to label each study participant's data records.

All interview audio files will be stored on the recorders; transcription will be done in house by contractor team members by listening to the recording device and transcribing to stand-alone computers that are not networked, taking care to remove any personally identifiable information (PII) that may have been transcribed accidentally. Data brought to study offices will be securely managed by securing the paper and recordings in separate locked offices, cabinets, drawers, and briefcases. Only project staff will have access to the records, study documents, and data. Electronic files will be password protected and stored on a secure server. No final interview transcript or other computerized data file will contain any personally identifiable information from the participant.

Each interview will be transcribed into an encrypted MS Word document. Transcripts and NVivo files for individual cases will be stored on and edited from a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer (without Internet access) at study offices. NVivo analysis files will be stored in a FISMA-compliant enclave on a dedicated data server. Backup files will be encrypted and maintained on flash drives securely kept under lock and key.

Authorized contractor staff will keep paper and audio files of the interviews as well as the completed interview guides, screeners, contact information and other project materials through the period of transcription, quantitative data entry, and QA/QC processes. Participant contact information will be destroyed after completing the transcription process. All consent documents will be maintained in locked cabinets within a secured, physical space, separate from other study data, of which only key study staff have access to records. All electronic study data (transcripts without PII) will be kept in encrypted or password protected files. Analysis will be done on secure network systems or stand-alone (non-networked) password protected computers in secure locations. Study participants will only be labeled with unique numeric ID numbers in the final computerized data sets.

To protect study participant identities, CDC has completed a Privacy Impact Assessment of the data system used by the contractor team (**Attachment 6**). The contractor team also completes an annual renewal process for their data system, and has a current Authority to Operate approval (**Attachment 6**). Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. The study data sharing and use agreement describes in detail how data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights (**Attachment 5**).

Only project staff will have access to the records, study documents, and data.

3. Methods to Maximize Response Rates and Deal with No Response

Contractor staff will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Participants will be identified through the PS17-1704 program staff who may have trusted relationships with eligible participants.
- A $40 token of appreciation will be provided to key participants upon completion of the interview.
- All recruitment materials indicate the voluntary nature of the study.

4. Tests of Procedures or Methods to be Undertaken

The research team includes experts with experience conducting HIV research with health departments, community-based organizations, vulnerable populations and qualitative research, including screening and interview development and testing. The contracting team will conduct pretesting of the screening tool and interviews on three to five mock respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and to estimate response burden for each respondent. Health department staff will be responsible for recruiting respondents. Non-CDC members of the research team will be responsible for collecting data, as well as for generating transcripts that contain no PII.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit 5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC IRB review; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC staff will neither collect data from nor interact with research participants. Data will be collected by members of contractor project staff listed. No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff. All members of the research team will work together to analyze the data and generate reports containing summaries of the findings.

Exhibit 5.1: Statistical Consultants

Team Member	Organization	Phone	Email
James Carey	CDC	404-639-1903	Jfc9@cdc.gov
Lamont Scales	CDC	404-639-8293	Wjg5@cdc.gov
Pilgrim Spikes	CDC	404-639-8075	Pus2@cdc.gov
Alisu Schoua-Glusberg	Research Support Services	847-864-5677	alisu@researchsupportservices.com
Casey Tesfaye	Research Support	847-864-5677	casey@researchsupportservices.com

	Services		
Paula Frew	University of Las Vegas	702-774-2400	paula.frew@unlv.edu
Laura Randall	Emory University	404-727-2994	laura.randall@emory.edu
Bryan Gale	IMPAQ International	443-259-5186	bgale@impaqint.com
Valerie Betley	IMPAQ International	443-259-5196	vbetley@impaqint.com

References

1. Centers for Disease Control and Prevention. NCHHSTP Atlas Plus, https://www.cdc.gov/nchhstp/atlas/index.htm. Accessed [November 14, 2018].