

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 under OMB #0920-1091

Section A: Supporting Statement

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- **Goals of the study:** This qualitative research study focuses on community-based organization (CBO) clients who are black/African American and Hispanic/Latino young men who have sex with men (YMSM) and young transgender youth (YTG). The goal of this study is to identify

factors that influence how clients use HIV prevention, care, and treatment services offered at CBOs located in Deep South states. These four CBOs are funded by CDC's existing PS17-1704 grant program to provide HIV prevention and care services to YMSM and YTG.

- **Intended use:** Study outcomes will be communicated to local stakeholders and CBO staff in positions to consider and implement site-specific improvements in their HIV prevention, care and treatment services. The results of this study are not intended to be generalized to the larger population. The results also will provide CDC an increased understanding of the factors that contribute to effective HIV prevention, care and treatment programs provided by CBOs in Deep South states.
- **Methods to be used to collect data:** Data will be collected from a total of 156 individuals through semi-structured, qualitative in-depth interviews (IDIs).
- **Subpopulations to be studied:** We will obtain data from 144 black/African American and Hispanic/Latino YMSM and YTG, aged 18-24, who previously have received HIV prevention, care or treatment services from CBOs. In addition, we will obtain data from 12 CBO staff involved with provision of HIV-related services to YMSM and YTG clients. These 144 client and 12 CBO staff will be sampled from four CBOs located in Miami/Ft. Lauderdale, Florida; Atlanta, Georgia; New Orleans/Baton Rouge, Louisiana; and Columbia, South Carolina.
- **How data will be analyzed:** Qualitative coding of 156 IDI transcripts using computer-assisted qualitative data analysis software.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for a qualitative extramural research study entitled, "Factors that Influence Use of 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) Living in the Deep South" under the Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States Generic Clearance (OMB #0920-1091, expires 09/30/2021). CDC sponsors this current data collection activity. Data collection will be carried out by the CDC's contractor, Research Support Services, in conjunction with its subcontracting partners.

An estimated 1.1 million persons aged 13 and older were living with HIV infection in the United States at the end of 2015, including an estimated 162,500 (15%) persons whose infections had not been diagnosed.¹ The southern U.S. in particular accounted for 45% of all people living with an HIV diagnosis and half of all new diagnoses in the U.S. in 2016, despite the South making up only one third (38%) of the U.S. population.² The "Deep South", defined as Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee and Texas, accounted for 40% of new diagnoses and a significant proportion (34%) of all persons living with HIV in the U.S.^{3,4} In just five years (2008-2013), the Deep South also had 21,308 HIV-related deaths, with a corresponding increase in new HIV diagnoses for 109,019 cases reported in the same time period.

The burden of HIV infection is disproportionately higher among some groups in the United States, such as men who have sex with men (MSM) and racial and ethnic minorities.⁵ Data show diagnoses among

young men who have sex with men (YMSM) of color remain high, especially among black/African American and Hispanic/Latino YMSM.² Among newly diagnosed youth (age 13 – 24), 81% were from male-to-male sexual contact; 55% of these newly diagnosed cases were black/African American males and 24% were Hispanic/Latino males.⁶ Although data for transgender people are not uniformly collected and information is lacking on the number or proportion of transgender people in the United States who are infected with HIV, a recent meta-analysis of individual studies estimated that 25% of young transgender women are living with HIV.⁷ Transgender youth (YTG) face numerous HIV prevention challenges, which include drug and alcohol use, mental health disorders, homelessness, unemployment, discrimination, violence, victimization, limited housing opportunities, and negative experiences with health care providers and settings.⁸ Together, these increase the likelihood of poor HIV prevention service utilization and poor HIV treatment outcomes.

Prior studies suggest that stigma, discrimination, higher levels of sexually transmitted infections, racial inequality and bias, legal impediments for sexual minorities, cultural issues, a lack of qualified medical care providers, poverty, and other financial barriers may prevent YMSM and YTG youth in the South from accessing HIV testing and prevention services, as well as HIV care and treatment for those living with HIV infection.^{9,10,11} In 2015, youth living with HIV infections had the lowest percentage of persons linked to HIV medical care within one and three months following diagnosis of any age group; they were also the age group with the lowest percentage of viral suppression at the end of 2014.¹²

Community-based organizations often play critical roles in assisting YMSM and YTG of color who otherwise would have few other options for obtaining HIV prevention, care, and treatment services. It therefore is essential to understand factors that influence the success of YMSM and YTG of color in accessing and using CBOs in their communities.

This project will conduct case studies of community-based organizations (CBOs) that provide HIV prevention, care, and treatment services to clients who are black/African American and Hispanic/Latino YMSM and YTG. For our study purposes, we especially are interested in CBOs that provide services to YMSM and YTG of color aged 18-24 years. This study will identify factors that influence how clients access and use HIV prevention, care, and treatment services offered at CBOs located in Deep South states. This study will yield a report that summarizes factors that influence the success of CBOs in providing HIV services to their clients. By learning from the experiences of CBO clients and staff running CBO programs, the proposed study will offer a unique perspective on how CBO programs function and the impact they have on their client's lives. We anticipate the findings from this study will be of practical use when creating new CBO services or when strengthening existing services.

The results of this proposed study therefore will help CBOs further improve their assistance to YMSM and YTG groups who historically have had difficulties obtaining HIV prevention, care, and treatment services.

2. Purpose and Use of the Information Collection

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.

The qualitative data collected through this study will be used to write a report that summarizes factors that influence how black/African American and Hispanic/Latino YMSM and YTG clients access and use HIV prevention, care, and treatment services offered at their local CBOs in the Deep South. These results will be communicated to relevant community public health personnel and CBO leaders in the study locations. These public health personnel and CBO leaders will be in a position to use the study results to further strengthen their local HIV prevention, care, and treatment programs that assist YMSM and YTG within their regions. Study outcomes will be communicated to local stakeholders and CBO staff in positions to consider and implement site-specific improvements in their HIV prevention, care and treatment services. The results of this study are not intended to be generalized to the larger population. The results also will provide CDC an increased understanding of the factors that contribute to effective HIV prevention, care and treatment programs provided by CBOs in Deep South states. The results also will provide CDC an increased understanding of the factors that contribute to effective HIV prevention, care and treatment programs provided by CBOs in different geographic locations within Deep South states. Given the information gathered will be from specific regions and agencies, the results shared in the summary report will have limited generalizability. The results shared in the summary report will be specific to the agencies.

The 12 CBO staff and 144 YMSM and YTG clients will be recruited for in-depth interviews (IDIs) across all four sites. Contractor team members involved with this study will identify eligible CBO staff by examining lists of CBO personnel. These 12 CBO staff will include individuals involved with provision of HIV prevention, care, or treatment-related services to their YMSM and YTG clients. Once project clearances have been obtained, we will request name and contact information for all staff on the list, and will use that list to recruit participants into the CBO staff sample. Participation in this study will not impact CBO staff job performance, and there is no requirement for the 12 staff members to participate in this study as a function of their job performance. No screening tool is needed for CBO staff participants because they will be purposively recruited based on the roles they play in the four CBOs.

Recruitment of the 144 YMSM and YTG clients will be accomplished by referral from CBO staff at each site. CBO staff will have study information as well as a set of study recruitment flyers with unique ID numbers to distribute to their YMSM and YTG clients (**Attachment 1**). The CBO staff will share this study information with their program's clients and give them a copy of one of the flyers. This information includes details on how a client can contact study staff, if they are interested in being a participant. However, the CBO staff will never learn which of their clients contacted study staff after referral. Likewise, CBO staff also will never learn which of their clients subsequently became enrolled as participants in the study. Finally, to help protect participant identities, CDC staff will never learn the identities of either the CBO staff or clients enrolled in the study. (For additional details on how we protect the identities of study participants, see the **Protection of the Privacy and Confidentiality of Information Provided by Respondents** section included below in this document.)

If a CBO client is interested in being a study participant, they will call study staff from the contractor team, using the information provided in the recruitment flyers (**Attachment 1**). Study staff will screen potential client participants for study eligibility with the CBO client screening tool (**Attachment 3a**). Eligible client participants who choose to enroll in the study will be scheduled for an interview

(Attachment 3b) at a time and location that is convenient to them. At the beginning of each interview with CBO staff or clients and before any data collection starts, study staff will review the study procedures with each participant. Participants will be asked to complete an informed consent form **(Attachment 2)**. There are two consent forms; one for eligible CBO clients and one for eligible CBO staff. The wording of these forms has been reviewed and approved by the CDC IRB **(Attachment 4a)**. CDC IRB protocol approval was received October 10, 2018.

We will use two semi-structured qualitative interview guides to collect information for this study, one for CBO clients, and the other for CBO staff **(Attachments 3b-c)**. Both types of interviews include a short, structured response section to collect participants' descriptive characteristics information as well as open-ended questions. The questions included on the staff interview guide and the client interview guide intentionally inquire about related topics. It is possible that the CBO staff and clients may not share identical knowledge, recollections, perspectives, or opinions. By asking parallel questions using the two interview guides, we will be able to compare and contrast similarities and differences between the CBO staff versus the CBO clients. For example, staff might believe one specific CBO activity is particularly helpful for their clients. But the CBO clients might disagree or highlight other program activities during their interviews. Likewise, CBO staff and clients may have differing ideas related to how clients access and use HIV prevention, care, and treatment services. Conducting the interviews with the CBO staff and clients will allow us to identify the similarities and differences in the two groups' perspectives.

For the CBO staff respondents, the interview guide begins with a series of structured response questions that elicit demographic and other basic descriptive characteristics of the respondent, including the role they have within the CBO **(Attachment 3c)**. In addition, the staff interview guide includes a series of open-ended questions. These items ask the staff person to describe their views on how clients learn about and use the CBO's services. This interview guide also has a series of questions related to barriers and facilitators that CBO clients may face when seeking CBO services, including stigma related to the clients' sexual orientation, gender identity, HIV status, or racial/ethnic backgrounds.

For the CBO clients, the interview guide also begins with a series of structured response questions, including age, ethnicity, race, education sexual orientation, sex at birth, gender identity, HIV status, and other descriptive characteristics **(Attachment 3b)**. Likewise, the client interview guide includes open-ended questions. These are designed to learn about how the client recalls learning about the CBO, why they began using the CBO's services, factors that make it easier or more difficult to obtain services at the CBO, and the role that stigma related to the client's sexual orientation, gender identity, HIV status, or racial/ethnic background may affect the services they seek and receive at the CBO.

Key variables to be explored through the participant interviews are described in Exhibit 2.1 below. All data collection instruments have been approved by the CDC IRB **(Attachment 4a)**.

Exhibit 2.1: Overview of Key Variables

CBO Staff (Att. 3c)	CBO YMSM and YTG Clients (Att. 3b)
<ul style="list-style-type: none"> • Staff sample descriptive characteristics • Staff perspectives on how clients learn about and use the CBO’s services. • Staff perspectives on general barriers and facilitators that CBO clients may face when seeking CBO services, • Staff perspectives on how stigma related to their clients’ sexual orientation may affect how they access and use CBO services. • Staff perspectives on how clients’ gender identity may affect how they access and use CBO services. • Staff perspectives on how clients’ HIV-negative or HIV-positive status may affect how they access and use CBO services. • Staff perspectives on how clients’ racial or ethnic identity may affect how they access and use CBO services. • Lessons learned about how CBOs can successfully provide HIV prevention, care, and treatment services to black/African American or Hispanic/Latino YMSM and YTG. 	<ul style="list-style-type: none"> • Client sample descriptive characteristics • Client perspectives on how they learn about and use the CBO’s services. • Client perspectives on general barriers and facilitators that they face when seeking CBO services, • Client perspectives on how stigma related to their sexual orientation may affect how they access and use CBO services. • Client perspectives on their gender identity may affect how they access and use CBO services. • Client perspectives on how their HIV-negative or HIV-positive status may affect how they access and use CBO services. • Client perspectives on how their racial or ethnic identity may affect how they access and use CBO services. • Client ideas about how CBOs can successfully provide HIV prevention, care, and treatment services to black/African American or Hispanic/Latino YMSM and YTG.

3. Use of Improved Information Technology and Burden Reduction

The contracting team will screen potential CBO client participants by telephone or in person. A client screening tool will be used by the contracting team when talking with potential CBO client respondents (**Attachment 3a**). Study staff from the contracting team will conduct individual IDIs at a time and location that is convenient to the participants. Telephone interviews or visual remote interviews (such as web or Skype interviews) are not a good vehicle for developing the necessary rapport between interviewer and client participant for a successful qualitative interview on a sensitive topic. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer’s ability to read both. Thus, the contracting team will conduct the individual IDIs in person.

A member of the study contractor team will invite CBO staff to participate, either by telephone or by email. No staff screening tool is needed with potential CBO staff respondents because they will be invited based on their job roles within the CBO (for example, staff who provide HIV-related services to the CBO’s YMSM or YTG clients). When possible, the contractor team will conduct face-to-face interviews with the CBO staff participants. However, this may not always be possible because of busy work schedules for the CBO staff. In those situations, some program staff may be conducted by phone instead of face-to-face.

CBO clients and CBO staff will all be asked to provide a signed consent form prior to doing the interview. Two versions of the form will be used for the two groups (**Attachment 2**). Both consent forms have been reviews and approved by the CDC IRB (**Attachment 4a**). After asking for and

receiving signed consent forms from the participant, the contracting team will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the participant (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the participant.

4. Efforts to Identify Duplication and Use of Similar Information

This study will gather information about factors that influence how black/African American and Hispanic/Latino YMSM and YTG access and use the HIV prevention, care, and treatment services provided CBOs located in Deep South states. As previously noted in the “**Circumstances Making the Collection of Information Necessary**” section of this document, public health studies have shown that black/African American and Hispanic/Latino YMSM and YTG are at high risk for acquiring HIV infection, especially in Deep South states. Likewise, prior information exists showing that black/African American and Hispanic/Latino YMSM and YTG often faces challenges in obtaining services that might help HIV-negative individuals avoid acquiring HIV infection. Prior evidence also suggests that HIV-positive black/African American and Hispanic/Latino YMSM and YTG have difficulty accessing HIV care and treatment services.

However, we are not aware of any previous studies that have collected information on factors that influence how black/African American and Hispanic/Latino YMSM and YTG access and use HIV prevention, care, and treatment services provided by CBOs in the Deep South, or in any other regions of the United States. CBOs often are unique and essential sources of HIV prevention, care, and treatment services for black/African American and Hispanic/Latino YMSM and YTG. To the Agency’s knowledge, the current proposed information collection will be the first study to examine these issues. The results obtained from the current proposed study will provide unique, novel, and useful information that CBOs and other public health stakeholders can use to improve HIV prevention, care, and treatment services for black/African American and Hispanic/Latino YMSM and YTG.

Thus, the Agency believes this proposed information collection is not captured elsewhere, and that no other data collection effort has been conducted or has been planned to collect similar information for this population in these jurisdictions. The Agency conducted a review of related studies and determined that this study is collecting unique information. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate these research questions.

5. Impact on Small Businesses or Other Small Entities

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

6. Consequences of Collecting the Information Less Frequently

This information collection will provide the primary qualitative data needed to understand how black/African American and Hispanic/Latino YMSM and YTG access and use HIV prevention, care, and treatment services provided by CBOs in the Deep South. If this case study were not conducted, it would not be possible to form an in-depth contextual understanding of factors that may affect the success of CBOs providing these services to these populations. Collecting this type of jurisdiction-specific information is important, as it will allow us to provide feedback to CBOs and other public health stakeholders that is relevant for improving HIV prevention, care, and treatment services offered by the CBOs. The total length of data collection is 3-4 months and data will only be collected once.

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

This data collection effort does not involve any special circumstances.

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

A 60 day FRN notice to solicit public comments was published for the Generic umbrella collection (0920-1091) in the Federal Register on 02/24/2015, Volume 80, Number 36, Page Number 9727-9728. No public comments were received.

In addition, Research Support Services and their subcontractors (IMPAQ International, and Emory Univ./Univ. of Nevada) were consulted for the development of this study (see Table below). There were no unresolved issues associated with the consultation process. Aside from the official 60 day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.

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9. Explanation of Any Payment or Gift to Respondents

Interview participants who are CBO staff will not receive token of appreciation funds. However, interview participants who are CBO clients will each receive a \$40 token of appreciation. Forty U.S. dollars has been used in prior OMB-approved collections under this generic umbrella mechanism including LEAP (OMB 0920-0840), LEAP Part II (OMB 0920-1091), and Data to Care (OMB 0920-1091) projects. In addition, this amount is consistent with similar studies and accounts for the inconvenience of travel and time. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of tokens of appreciation is expected to enhance survey response rates without biasing responses.^{18, 19}

Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups into research. In a recent study of recruitment and retention of black men who have sex with men by a community-based organization, recruiters found it difficult to obtain information from participants because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to an HIV prevention program. However, in this study, offering a token of appreciation improved participation.²⁰ In addition, a meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among this group.²¹

Remuneration has been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), which included similar populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates. Tokens of appreciation also were successfully used in prior information collections completed under this existing generic ICR, and they helped encourage respondent recruitment. Numerous other studies have shown that tokens of appreciation can significantly increase response rates and the use of tokens of appreciation is expected to enhance survey response rates without biasing responses. This improves the validity and reliability of the data, which is of utmost importance in this scientific study. In addition, HIV has a stigma that other health issues do not have, which makes it difficult to recruit participants for research when compared to other diseases.

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

The CDC Privacy Officer has assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does apply to the overall information collection. CDC has completed a Privacy Impact Assessment of the data system used by the study contractor team (**Attachment 6**).

Potential CBO client respondents will be screened 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. All participants will be informed that the information collected during the interview will not be attributed to the participant. After the consent process is finished, the interview will begin. 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**).

Personally identifiable information (PII) including names, addresses, phone numbers, email addresses, will be electronically deleted by Atlas Research Inc., and Research Support Services Inc., before data are transferred to CDC. Therefore, data provided by CDC for release will not contain PII.

All quotations by participants used in publications from qualitative data where the research population contains 40 or fewer participants can only be identified using gender, transmission group, age category (not specific age), and race/ethnicity (if more than one race is provided, use ‘multi-race’). For example, quotes will follow this format: “Lorem ipsum dolor sit amet, duo ei dicta theophrastus intellegebat. Est meliore liberavisse cu. An duo populo laboramus, eam iusto appareat no. Eum probatus evertitur in. Ad ius feugiat consectetur, eu liber maiorum mea. Nec an alia iriure.” Hispanic/Latino MSM, 18-24 years old.

Atlas Research Inc., and Research Support Services Inc., will conduct data cleaning on all data sets prior to delivery to the CDC. This process will ensure that all PII (including indirect identification data) are deleted from the data. All data will be retained until analysis is complete and for up to two years after publication. At that time, users must delete all data stored on their servers. CDC will store complete de-identified data on a secure server that is accessible through the Division of HIV Prevention, Prevention Research Branch.

Only project staff will have access to the records, study documents, and data. CDC staff will not be involved with sample recruitment and will never know the identities of any study respondents.

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

IRB Approval

This study has been reviewed and approved by the CDC IRB (**Attachment 4a**). The Emory University IRB also declared that no IRB review is required (**Attachment 4b**).

Sensitive Questions

This study is an initiative to identify factors that influence how black/African American and Hispanic/Latino YMSM and YTG clients access and use HIV prevention, care, and treatment services offered at CBOs located in Deep South states. As such, our information collection entails measurement of HIV-related information. All contracting staff will be trained to provide participants with referrals for prevention and care, such as mental health care organizations, as needed. We will inform all participants that they may skip any question or stop interviews at any time for any reason. Sensitive information is not transferred to CDC, and the results are transmitted to CDC in aggregate.

12. Estimates of Annualized Burden Hours and Costs

The recruitment and enrollment period is four months. This data collection will include 156 individuals. 144 individuals will be adult YMSM and YTG clients 18-24 years of age who have previously used HIV

prevention, care, or treatment services at the four CBOs. We expect to screen 288 CBO clients, and we expect 50% to be eligible and to participate in the data collection, which yields a final client sample size of 144. Contractor staff will screen potential CBO client participants for eligibility by phone, which will take approximately five minutes (**Attachment 3a**). The CBO client interview (**Attachment 3b**) will take 60 minutes to complete and will be administered once.

We will also interview 12 CBO staff. The CBO staff interview (**Attachment 3c**) will take 60 minutes to complete and will be administered once. No separate screening instrument will be used to identify eligible CBO staff because they will be identified directly through existing CBO staff rosters.

Exhibits 12.1 and 12.2 provide further details about how the estimates of burden hours and costs were calculated. The estimated annualized burden is 180 hours.

12A. Estimated Annualized Burden Hours

Exhibit 12.2: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (hours)	Total Burden Hours
General Public-Adults	CBO Client Screener (Att. 3a)	288	1	5/60	24
General Public-Adults	CBO Client Interview (Att. 3b)	144	1	1.0	144
General Public-Adults	CBO Program Staff Interview (Att. 3c)	12	1	45/60	9
Total					177

12B. Estimated Annualized Burden Costs

The annualized costs to the participants are described in Exhibit 12.2. The United States Bureau of Labor Statistics’ employment and wages estimates from April 6, 2018 (<https://www.bls.gov/news.release/empsit.t19.htm>) were used to estimate the hourly wage rate for “other services” provided by the general public for the purpose of this GenIC request. The total estimated cost of the burden to participants is approximately \$4,374.00. This cost represents the total burden hours of general participants multiplied by the average hourly wage rate (\$24.30).

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	CBO Client Screener (Att. 3a)	24	\$24.30	\$583.20
General Public-Adults	CBO Client Interview (Att. 3b)	144	\$24.30	\$3,499.20

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	CBO Program Staff Interview (Att. 3c)	9	\$24.30	\$218.70
Total \$4, 301.10				

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

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

14. Annualized Cost to the Federal Government

Exhibit 14.1 provides the annualized cost to the government, which totals \$369,288.88 using the 2018 Atlanta locality salary schedule. CDC supports costs for HIV prevention program task orders using funds budgeted for these purposes. Additional expenses may be incurred by CDC for attending site visits. Managing the project, providing technical assistance, monitoring and analyzing the submitted data, and generating assorted reports will require the expertise of three CDC staff.

Exhibit 14.4: Annualized Cost to the Government (2017 scale)

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs	CDC, Project Officer (GS-14, 0.20 FTE)	\$21,656.20
	CDC Scientist (GS-13, 0.20 FTE)	\$18,326.20
	CDC Scientist (GS-13, 0.20 FTE)	\$18,326.20
	Subtotal, Direct Costs	\$58,308.60
Contract Costs	Annual Contract Costs (RSS, #200-2013-57341)	\$310,977.28
	TOTAL COST TO THE GOVERNMENT	\$ 369,288.88

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of participants collected in the first part of the interviews. Data collection will occur between April-July 2019, analyses will be carried out in August-September 2019, and the final data set and report will be submitted in March 2020. The project timeline is detailed in exhibit 16.1.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol	October 2017 – May 2018; CDC IRB protocol approval was received October 10, 2018
OMB Submission	December 2018

Recruitment	1-4 months after OMB Approval (February-March 2019)
Data Collection	1-5 months after OMB Approval (April-July 2019)
Data analysis finalized	5-7 months after OMB Approval (August-September 2019)
Draft report and final report written	9-11 months after OMB approval (October-December 2019)
Final data set and final report submitted to CDC	12 months after OMB Approval (March 2020)

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other PII, and locations will be removed) qualitative database for this study along with the corresponding data documentation. Public access to the final 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 de-identified data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights. A copy of the Data Use Plan is provided (**Attachment 5**).

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

References

Dailey AF, Hoots BE, Hall HI, Song R, Hayes D, Fulton P, Prejean J, Hernandez AL, Koenig LJ, Valleroy LA. Vital Signs: Human Immunodeficiency Virus testing and diagnosis delays — United States. *MMWR* 2017;66:1-7.

² AIDSvu. Deeper Look: HIV in the South. 2017. <https://aidsvu.org/aidsvu-in-use/deeper-look/south/>

³ Centers for Disease Control and Prevention. HIV Surveillance Report: Diagnoses of HIV Infection in the United States and Dependent Areas, 2016 ; vol. 28. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published November 2017.

⁴Centers for Disease Control and Prevention. HIV among Youth. <https://www.cdc.gov/hiv/group/age/youth/index.html>.

⁵ Dowshen, N, Lee, SS, Castillo, M, Hawkins, L, Barg, FK. Barriers and Facilitators to HIV Prevention, Testing, and Treatment among Young Transgender Women. *Journal of Adolescent Health*, Volume 58, Issue 2. November 2016.

⁶ Centers for Disease Control and Prevention. HIV among Transgender People. <https://www.cdc.gov/hiv/group/gender/transgender/>. 2017.

⁷ Centers for Disease Control and Prevention. Sexual Identity, Sex of Sexual Contacts, and Health-Related Behaviors Among Students in Grades 9-12 - United States and Selected Sites, 2015. *MMWR Surveill Summ*. 2016 Aug 12;65(9):1-202. doi: 10.15585/mmwr.ss6509a1

- ⁸ Reif, Susan ; Safley, Donna ; Wilson, Elena ; Whetten, Kathryn (2016) HIV/AIDS in the U.S. Deep South: Trends from 2008-2013. Publisher: Southern HIV/AIDS Strategy Initiative. <https://southernaids.files.wordpress.com/2011/10/hiv-aids-in-the-us-deep-south-trends-from-2008-2013.pdf>.
- ⁹ Reif S, Whetten K, Lowe K. HIV and AIDS in the Deep South. *American Journal of Public Health*. 2006;96(6):970-973.
- ¹⁰ Reif, Susan; Safley, Donna; McAllaster, Carolyn; Wilson, Elena; Whetten, Kathryn (2017) State of HIV in the US Deep South. Publisher: Southern HIV/AIDS Strategy Initiative. Available at: <https://dukespace.lib.duke.edu/dspace/handle/10161/13807>.
- ¹ Wohl DA, Kuwahara RK, Javadi K, Kirby C, Rosen DL, Napravnik S, Farel C. financial Barriers and Lapses in Treatment and Care of Hiv-infected Adults in a Southern State in the United States. *AIDS patient care and STDs*. 2017 Nov 1;31(11):463-9.
- ² Turan B, Budhwani H, Fazeli PL, Browning WR, Raper JL, Mugavero MJ, Turan JM. How does stigma affect people living with HIV? The mediating roles of internalized and anticipated HIV stigma in the effects of perceived community stigma on health and psychosocial outcomes. *AIDS and Behavior*. 2017 Jan 1;21(1):283-91.
- ³ Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2015. *HIV Surveillance Supplemental Report 2017*;22(No. 2). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published July 2017.
- ⁴ AIDSvu. City and State Profiles. <https://aidsvu.org/local-statistics/>. Accessed April 2018.
- ⁵ Centers for Disease Control and Prevention. Diagnosis of HIV infection in the United States and its dependent areas, 2014. 2015. Available from: <http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf>.
- ⁶ Florida Department of Health. Monthly HIV/AIDS Surveillance Report October 2015. *HIV/AIDS Surveillance 2015*; Available from: http://miamidade.floridahealth.gov/programs-and-services/infectious-disease-services/hiv-aids-services/_documents/hiv-surveillance-monthly-report-2015-10.pdf.
- ⁷ Georgia Department of Public Health. HIV Surveillance Fact sheet 2015 <http://dph.georgia.gov/georgias-hivaidsepidemiology-surveillance-section>. Published April 2017. Accessed [April 23, 2017].
- ⁸ Georgia Department of Public Health, HIV/AIDS Epidemiology Section HIV Surveillance Summary, Georgia 2015, <https://dph.georgia.gov/data-fact-sheet-summaris>, Published March 2017. Accessed [April 23, 2017].
- ⁹ Sullivan PS, Rosenberg ES, Sanchez TH, Kelley CF, Luisi N, Cooper HL, et al. Explaining racial disparities in HIV incidence in black and white men who have sex with men in Atlanta, GA: a prospective observational cohort study. *Annals of epidemiology*. 2015;25(6):445-54.
- ²⁰ Data USA. Atlanta, GA – Demographics (Race & Ethnicity) [Cited July 2016] <http://datausa.io/profile/geo/atlanta-ga/#demographics>
- ²¹ Louisiana Department of Health. 2014 STD/HIV Surveillance Report. http://new.dhh.louisiana.gov/assets/oph/HIVSTD/2014_STDHIV_SURVEILLANCE_REPORT.pdf.
- ²² Centers for Disease Control and Prevention. HIV Surveillance Report, 2015; vol. 27. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published November 2016.
- ²³ AIDSvu. Columbia Highlights. <https://aidsvu.org/state/south-carolina/columbia/>
- ²⁴ Patton, M. (1990) *Qualitative evaluation and research methods*. (pp. 169-186). Beverly Hills, CA: SAGE.
- ²⁵ McLellan, Eleanor, MacQueen, Kathleen M., and Neidig, Judith L. 2003. Beyond the Qualitative Interview: Data Preparation and Transcriptions. *Field Methods* 15(1):63-84.

²⁶ Abreu DA, Winters F. Using monetary incentives to reduce attrition in the survey of income and program participation. . Proceedings of the Survey Research Methods Section of the American Statistical Association 1999.

²⁷ Shettle C, Mooney G. Monetary incentives in U.S. government surveys. *Journal of Official Statistics* 1999;15(2):231-50.

²⁸ Painter TM, Ngalame PM, Lucas B, Lauby JL, Herbst JH. Strategies used by community-based organizations to evaluate their locally developed HIV prevention interventions: Lessons learned from the CDC's innovative interventions project. *AIDS Educ Prev* 2010;22(5):387-401.

²⁹ Yancey AK, Ortega AN, Kumanyika SK. Effective recruitment and retention of minority research participants. *Annu Rev Public Health* 2006;27:1-28.

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