

Understanding Barriers and Facilitators to HIV Prevention, Care, and Treatment

Generic Information Collection request under 0920-0840

Section A: Supporting Statement

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Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)/Division of HIV/AIDS Prevention is requesting approval of a sub-collection under a generic approval (Formative Research and Tool Development, OMB #0920-0840, expiration 2/29/2016), for a data collection entitled, “Understanding Barriers and Facilitators to HIV Prevention, Care, and Treatment” to collect data to assess barriers and facilitators to HIV prevention, care, and treatment from the prospective of HIV providers and PLWH.

The proposed data collection instruments will be used to gather information about the barriers and facilitators to HIV prevention, care, and treatment that could a) help improve retention and engagement in HIV care and b) affect the process of connecting HIV patients to supportive services. Over the course of 5 months this study will collect qualitative data from, 1) thirty (30) HIV providers; 2) eighty (80) persons living with HIV (PLWH); and 3) twenty (20) of their HIV-discordant partners. The recruitment of HIV providers will be conducted in three major metropolitan areas (Atlanta, GA; Baltimore, Maryland; Washington, DC), conducted by contractor Atlas, and sub-contractors ABT Associates. Recruitment of PLWH and their HIV-discordant partners will be conducted in five major metropolitan areas (Atlanta, GA; Baltimore, Maryland; Chicago, Illinois; Los Angeles, California; Washington, DC), conducted by contractor Research Support Services (RSS), and sub-contractors IMPAQ, and Emory University. Findings from the data collection will be used to develop better programs and policies for HIV prevention, care, and treatment of PLWH. Findings will inform CDC, policymakers, prevention practitioners, and researchers about barriers and facilitators to HIV prevention, care, and treatment for PLWH in order to better develop methods, instrumentation, supporting programs and policies.

With only one in four PLWH in the United States achieving viral suppression, there are clear opportunities to strengthen the delivery of services to those living with HIV across the continuum of care.¹ In the United States, there is an estimated 1.15 million PLWH, and approximately 50,000 new infections each year. More than one in three PLWH are not successfully linked to care within the first three months of diagnosis.⁴ Among those aware of their HIV infection, less than half are adequately engaged in HIV care.⁵ It is estimated that 60% of PLWH in the US are not receiving consistent HIV care due to delayed diagnosis, inadequate linkage to care and barriers to retention to HIV care.⁵ These statistics represent significant lost opportunity for treatment outcomes supporting improved health status and lower rates of HIV transmission. If the United States is to deter the epidemic, it is critical that we increase our understanding of the factors that affect engagement and retention in HIV care and connection to social services for PLWH.³ In addition, we must identify why some individuals do or do not test and seek medical care at HIV diagnosis, stay in or drop out of care, and may or may not adhere to antiretroviral treatment (ART); and how persons living with HIV (PLWH) protect their partners when in HIV-discordant relationships.

Advances in ART have made it possible for persons living with HIV to have longer, healthier, and productive lives. A consistently suppressed HIV viral load resulting from ART can reduce morbidity and mortality, and lower the probability of transmitting HIV to an uninfected sex partner¹. HIV testing is the entry point to the HIV care and treatment continuum that includes diagnosis through testing, linkage to and retention in continuous HIV medical care, and appropriately timed ART to achieve viral suppression¹.

HIV disproportionately affects racial and ethnic minority populations in the United States. Among all racial/ethnic groups, blacks and Latinos continue to be the most impacted populations. In 2010, blacks accounted for only 12.3% of the US population, but comprised 46% of all new HIV infections; comparable figures for Latinos in 2010 were 15% and 20.5%, respectively². Blacks and Latinos often experience disparities in access to high-quality HIV care which may be due to poverty, low health literacy, discrimination, and other HIV-related social determinants of health^{3,4}. Moreover, these populations commonly experience delayed entry into HIV care, lower retention levels once in care, poor adherence to ART, and have excess HIV-related morbidity and mortality^{1,4,5,6,7,8}.

To successfully engage racial/ethnic minority persons living with HIV (PLWH) at every stage of the HIV care and treatment continuum, we must understand the contextual factors underlying these issues to help identify new opportunities for intervention, and improve prevention, care and treatment outcomes in racial/ethnic minority communities.

Data collection instruments are included with this submission as attachments. HIV providers will be purposively sampled and selected from a pre-determined list. Recruiters will schedule in-depth interviews at time and place convenient to HIV providers. Interviewers will review study information and consent form (**Attachment 3a-b**), and administer demographic questionnaire and in-depth interview (**Attachments 2a-2b**). We will recruit PLWH using recruitment flyers (see **Attachments 5a-5t**). To determine eligibility of interested PLWH and HIV-discordant partners, we will administer recruitment screeners (**Attachments 2c-2f**). After screening for eligibility, recruiters will collect contact information for PLWH and HIV-discordant partner (if the PLWH indicates their partner is interested in participating) on a separate form (see **Attachments 2g-2j**). Using this contact information, recruiters will schedule an in-person

¹ Cohen et al., Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *New England Journal of Medicine*, 2011. 365(6): p. 493-505.

² Hall, et al., Continuum of Care: Differences in Care and Treatment by sex and race/ethnicity in the United States [abstract # FRLBX05]. Presented at AIDS 2012, Washington D.C.

³ Aziz M, Smith KY. Challenges and Successes in Linking HIV-infected Women to Care in the US. *Clinical Infectious Diseases* 2011; 52:S23 1-7

⁴ Sharpe et al., Social Determinants of HIV/AIDS and Sexually Transmitted Diseases Among Black Women: Implications for Health Equity. *J Women's Health* 2012;21:249-54

⁵ Christopoulos et al., Linkage and Retention in HIV Care Among Men Who Have Sex With Men in the U.S. *Clin Infect Dis*, 2011; 52:S214-S222

⁶ Dennis et al., Late Entry to HIV Care Among Latinos Compared with Non-Latinos in a Southeastern US Cohort. *Clin Infect Dis*, 2011 Sept;53(5):480-7

⁷ Millett et al., Greater Risk for HIV Infection of Black Men Who Have Sex With Men: A Critical Literature Review. *AJPII* 2006; 96(6): 1007-19;

⁸ Millett et al., Explaining Disparities in HIV Infection Among Black and White Men Who Have Sex With Men: A Meta-Analysis of HIV Risk Behaviors. *AIDS* 2007;21 (15):2083-91

interview at a time and place convenient to them. Interviewers will review consent forms (**Attachments 3a-3e**), administer the in-depth interview protocols (**Attachments 2k-2n**). PLWH and their HIV discordant partners will have the option of having all procedures (i.e. forms, calls, and in-depth interview) in English or Spanish. Key variables to be explored are described in Exhibit A1.1.

Exhibit A1.1 Items of Information to be Collected

Variables to be explored	Data collection tool and citation	Study Related Procedures	Target Population
Age; Race/Ethnicity; Gender; Sexual Orientation; Provider credentials/ certifications	2a. Provider Demographic Questionnaire	In-Depth Interviews	HIV Providers
Definitions of engagement; approaches to engaging patients; barriers to engaging patients; relationships with other providers; monitoring patients; innovative practices;	2b. Provider In-Depth Interview Guide	In-Depth Interviews	HIV Providers
Demographics; HIV experience & history; HIV treatment; general health; referral history & experience	2k. PLWH In-Depth Interview Guide-English	In-Depth Interviews	PLWH
Demographics; HIV experience & history; HIV treatment; general health; referral history & experience	2l. PLWH In-Depth Interview Guide-Spanish	In-Depth Interviews	PLWH
Demographics; HIV testing history; partner status disclosure; partner care & treatment; transmission concerns & risk; PrEP knowledge	2m. HIV-discordant Partners In-Depth Interview Guide-English	In-Depth Interviews	HIV-Discordant Partners
Demographics; HIV testing history; partner status disclosure; partner care & treatment; transmission concerns & risk; PrEP knowledge	2n. HIV-discordant Partners In-Depth Interview Guide-Spanish	In-Depth Interviews	HIV-Discordant Partners

2. Purpose and Use of Information Collection

The overall purpose of the study is to assess barriers and facilitators to HIV prevention, care, and treatment for HIV providers and PLWH. We will use the data to develop better programs and policies for HIV prevention, care, and treatment of persons living with HIV/AIDS.

3. Use of Improved Information Technology and Burden Reduction

Due to the sensitive nature of the topics in our interviews, group data collection formats (e.g., focus groups) would not be conducive to obtaining rich information on issues such as reasons for refusing or dropping out of treatment. For this reason, we will conduct individual interviews. Telephone interviews or visual remote interviews (such as web or Skype interviews) are more difficult for the target population and not a good vehicle for developing the necessary rapport between interviewer and respondent 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, we will conduct the individual, in-depth interviews (IDIs) in person. After asking for and receiving permission from the respondent, we will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent.

Following an in-person interview, a project team member will transcribe the recording. We anticipate that Spanish language interviews will be conducted in Chicago and Los Angeles. They will be transcribed directly into English by an experienced transcriber/translator at project site (see **Attachment 6** for Spanish Translation Certification).

4. Efforts to Identify Duplication and Use of Similar Information

The interviews will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other survey data collection effort has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of the contract, and determined that this study is collecting unique information from the populations. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

5. Impact on Small Businesses or Other Small Entities

We will ask clinics, including potentially some small clinics, to aid in recruiting potential respondents by identifying eligible potential participants and providing them with a recruitment flyer. We do not anticipate substantial burden.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative data needed for federal policy makers to assess barriers and facilitators to HIV prevention, care, and treatment. If this evaluation were not

conducted, it would not be possible to determine barriers and facilitators among HIV providers and PLWH encounter regarding HIV prevention, care, and treatment. The length of data collection is 2-3 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 notice to solicit public comments was published in the Federal Register on August 2, 2012, Vol. 77, No. 149 (Generic 0920-0840). No public comments were received.

9. Explanation of any Payment or Gift to Respondents

We will provide PLWH and their HIV-discordant partners who participate with a token of appreciation totaling \$40 to encourage their participation, and convey appreciation for contributing to this important study. These will be a gift certificate in Atlanta, Georgia and cash in the other locations. 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 modest tokens of appreciation is expected to enhance survey response rates without biasing responses.^{9,10} 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, (e.g. cancer, diabetes, obesity). One study on research participant recruitment in Hispanic communities, researchers noted that the stigma related to HIV/AIDS is a major barrier in subject recruitment for HIV/AIDS behavioral research.¹¹ Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups in to research. Barriers cited related to recruitment of minorities included (1) lack of trust among minority communities towards the medical research process and research^{12,13,14} (2) a lack of competence among researchers to use culturally competent approaches for recruitment and¹⁵ (3) reluctance to participate due to inconvenience and a lack of time^{15,16}. In a recent study of recruitment and retention of Black men who sleep with men (BMSM) by a Community Based

⁹ Abreu, D. A., & Winters, F. (1999). 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*.

¹⁰ Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics*, 15, 231–250.

¹¹ Shedlin, M. G., Decena, C. U., Mangadu, T., & Martinez, A. (2011). Research participant recruitment in Hispanic communities: Lessons learned. *Journal of Immigrant and Minority Health*, 13 (2), 352-360.

¹² Quinn S. C (1997). *Belief in AIDS as a form of genocide: Implications for HIV prevention programs for African Americans*. *Journal of Health Education*, 28,(Suppl. 6)S6–S11

¹³ Wrobel AJ, Shapiro NEK. Conducting research with urban elders: Issues of recruitment, data collection, and home visits. *Alzheimer Dis Assoc Disord*. 1999;13(suppl 1):S34–S38

¹⁴ Gauthier, M. A., & Clarke, W. P. (1999). Gaining and sustaining minority participation in longitudinal research projects. *Alzheimer Disease and Associated Disorders*, 13(Suppl. 1), S29-S33

¹⁵ Goodwin, P. Y., Williams, S. W., & Dilworth-Anderson, P. (2006). The role of resources in the emotional health of African American women: Rural and urban comparisons. In R. T. Coward, L.A. Davis, C.H. Gold, H. Smiciklas-Wright, L.E. Thorndyke, & F.W. Vondracek, (Eds.). *Rural women's health: Mental, behavioral, and physical issues* (pp. 179 — 196). New York: Springer

Organization (CBO), recruiters found it difficult to retain information from the BSM 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 program¹⁶. Concern with potential social labeling and HIV-related stigma also may have contributed to their hesitation¹⁶. Some of those who were screened provided incorrect contact information, making it difficult or impossible to locate them later¹⁶. In this study, some agreed to participate in the evaluation because of the tokens of appreciation that was offered¹⁶. Respondents will receive the token of appreciation regardless of whether they complete the interview or skip any questions.

Monetary tokens of appreciation such as gift cards will not be offered for participation to HIV providers in the study. Many HIV providers consider their participation to be part of their role as health care workers to provide feedback such as that collected in the interviews. Instead, we will work with each HIV providers to provide a summary report of the study findings among all HIV providers. These data are anticipated to be of higher value to providers than a minimal financial token of appreciation. Similar procedures have been used successfully with a similar population of HIV providers in other studies by our team.

10. Assurance of Confidentiality Provided to Respondents

We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the evaluation team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the extent permitted by law.

10.1 Privacy Impact Assessment Information

As the nature of this study is to better understand barriers to HIV treatment, we are sensitive to the need to protect personal health information (PHI). To ensure that respondents' PHI is protected, we take several measures to separate personally identifiable information (PII) from study-related data. All respondents will receive unique identification codes which will be stored separately from PII. Contact information collected for the purposes of recruiting (i.e., name and telephone number) will be collected and stored securely and separately from responses to screening or interview questions. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. We will be prepared to describe these procedures in full detail and to answer any related questions raised by interviewees.

Access to all data that identify respondents (or such keys that link de-identified codes to personal information) will be limited to research staff that has a data collection or analysis role in the project. Such data will be needed only for scheduling interviews with respondents, and will not be used in the analyses. Transcripts will be completed on password protected standalone (non-networked) computers without internet access. Access to the transcript files on these computers will require password, and will only be allowed for staff working on this project and with a need

¹⁶ Painter, T. M., Ngalame, P. M., Lucas, B., Lauby, J. L., & Herbst, J. H. (2010). Strategies used by community-based organizations to evaluate their locally developed HIV prevention interventions: Lessons learned from the CDC's innovative interventions project. *AIDS Education and Prevention*, 22(5), 387-401.

to access. No PII will be included in the transcription. If the respondent divulges PII during the interview, the transcriber will convert the PII to bracketed non-PII descriptor information (i.e., [Daughter's Name]). Although transcripts will *not* contain PII, all transcripts will also be encrypted. No names or identifiers will be used when transcribing the data. Any data sent to CDC will not contain personal identifiers or any other identifier that would allow individual identification of study respondents.

In conjunction with the data policy, members of contractor project staff are required to:

- Comply with a Privacy Pledge and Security Manual procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the Project Director, and the organizational Security Officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the Project Directors and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by the project staff cover all aspects of data handling for hard copy and electronic data. Transcriptions (stripped of PII) will be stored on encrypted flash drives. Additional information about the security protocols for all materials and transcripts can be found in the Information Security Plan (**Attachment 7a-7b**) submitted with this document. We will investigate immediately if any item is delayed or lost. When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. Unless otherwise required by CDC, these documents will be destroyed when no longer needed for the project.

11. Justification for Sensitive Questions

This study is an initiative aimed to assess barriers and facilitators of HIV prevention, care, and treatment. As such, our study entails measurement of sensitive HIV-related information. Understanding the slight possibility of emotional response or anxiety on the part of the respondent (PLWH or HIV-discordant partner), all staff will be trained to provide respondents with city-specific hotlines for HIV and mental health care organizations as needed. No sensitive information will be collected during the semi-structured interviews with HIV care provider respondents, about the people they work with, or their patients. We will inform all respondents that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimated Annualized Burden Hours

Exhibits A12.1 and A12.2 provide details about how the estimates of burden hours and costs were calculated. We calculated the overall burden per respondent by multiplying the frequency of response by the time to complete each data collection item. We anticipate that consent forms and screener forms to take 5 minutes to complete each. HIV providers will be selected from a pre-determined eligible list and will not incur additional screening time. We anticipate 50 percent of PLWH and their HIV-discordant partners screened will be eligible for the study. Demographic Questionnaires (15 minutes) and In-depth interviews (45 minutes) for HIV providers are expected to take a total of 60 minutes (1 hour) total. In-depth interviews for PLWH and their HIV-discordant partners are expected to take 60 minutes (1 hour) to complete. We will complete 30 HIV provider in-depth interviews and 100 in-depth interviews with PLWH and their HIV-discordant partners. We anticipate screening 200 potential respondents. The total number of burden hours is 167.

Exhibit A12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
HIV Providers	3a. Provider Information Sheet and Consent Form	30	1	5/60	3
HIV Providers	2a. Provider Demographic Questionnaire	30	1	15/60	8
HIV Providers	2b. Provider In-Depth Interview Guide	30	1	45/60	23
General Public-Adults	2c. PLWH Study Screener-English	140	1	5/60	12
General Public-Adults	2d. PLWH Study Screener-Spanish	20	1	5/60	2
General Public-Adults	2e. HIV-discordant Partners Study Screener-English	30	1	5/60	3
General Public-Adults	2f. HIV-discordant Partners Study Screener-Spanish	10	1	5/60	1
General Public-Adults	2g. PLWH Contact Information Form-English	70	1	1/60	2
General Public-Adults	2h. PLWH Contact Information Form-Spanish	10	1	1/60	1
General Public-Adults	2i. HIV-discordant Partners Contact Information Form-English	15	1	1/60	1

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	2j. HIV-discordant Partners Contact Information Form-Spanish	5	1	1/60	1
General Public-Adults	3b. PLWH Consent Form-English	70	1	5/60	6
General Public-Adults	3c. PLWH Consent Form-Spanish	10	1	5/60	1
General Public-Adults	3d. HIV-discordant Partners Consent Form-English	15	1	5/60	2
General Public-Adults	3e. HIV-discordant Partners Consent Form-Spanish	5	1	5/60	1
General Public-Adults	2k. PLWH In-Depth Interview Guide-English	70	1	1	70
General Public-Adults	2l. PLWH In-Depth Interview Guide-Spanish	10	1	1	10
General Public-Adults	2m. HIV-discordant Partners In-Depth Interview Guide-English	15	1	1	15
General Public-Adults	2n. HIV-discordant Partners In-Depth Interview Guide-Spanish	5	1	1	5
Total					167

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A12.B. The United States Department of Labor Statistics May, 2012 http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the general public and Health diagnosing and treating practitioners for the purpose of this GenIC request. The total estimated cost of the burden to respondents is approximately \$4,127.19 per year (for a single data collection effort). This cost represents the total burden hours to HIV providers multiplied by the average hourly wage rate for Health diagnosing and treating practitioners (\$35.29) and adding that to the total burden hours of remaining respondents multiplied by the average hourly wage rate (\$22.01). We assume this estimate is higher than what it may actually be based on data from the Bureau of Labor Statistics' Current Population Survey in which respondents who identified as Black or African

American and respondents who identified as Hispanic or Latino Ethnicity reported lower median weekly earnings than respondents who identified as White¹⁷.

Exhibit A12.B. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
HIV Providers	3a. Provider Information Sheet and Consent Form	3	\$35.29	\$105.87
HIV Providers	2a. Provider Demographic Questionnaire	8	\$35.29	\$282.32
HIV Providers	2b. Provider In-Depth Interview Guide	23	\$35.29	\$811.67
General Adults	Public- 2c. PLWH Study Screener-English	12	\$22.01	\$264.12
General Adults	Public- 2d. PLWH Study Screener-Spanish	2	\$22.01	\$44.02
General Adults	Public- 2e. HIV-discordant Partners Study Screener-English	3	\$22.01	\$66.03
General Adults	Public- 2f. HIV-discordant Partners Study Screener-Spanish	1	\$22.01	\$22.01
General Adults	Public- 2g. PLWH Contact Information Form-English	2	\$22.01	\$44.02
General Adults	Public- 2h. PLWH Contact Information Form-Spanish	1	\$22.01	\$22.01
General Adults	Public- 2i. HIV-discordant Partners Contact Information Form-English	1	\$22.01	\$22.01
General Adults	Public- 2j. HIV-discordant Partners Contact Information Form-Spanish	1	\$22.01	\$22.01
General Adults	Public- 3b. PLWH Consent Form-English	6	\$22.01	\$132.06
General Adults	Public- 3c. PLWH Consent Form-Spanish	1	\$22.01	\$22.01

¹⁷ BLS, "Usual Weekly Earnings of Wage and Salary Workers: Third Quarter 2013," <http://www.bls.gov/news.release/wkyeng.toc.htm>.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	3d. HIV-discordant Partners Consent Form-English	2	\$22.01	\$44.02
General Public-Adults	3e. HIV-discordant Partners Consent Form-Spanish	1	\$22.01	\$22.01
General Public-Adults	2k. PLWH In-Depth Interview Guide-English	70	\$22.01	\$1,540.70
General Public-Adults	2l. PLWH In-Depth Interview Guide-Spanish	10	\$22.01	\$220.10
General Public-Adults	2m. HIV-discordant Partners In-Depth Interview Guide-English	15	\$22.01	\$330.15
General Public-Adults	2n. HIV-discordant Partners In-Depth Interview Guide-Spanish	5	\$22.01	\$110.05
Total				\$4,127.19

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

There are no costs to respondents for participating in this survey. All data collection costs for contacting the respondents or record keepers are borne by the federal government through the data collection contractors.

14. Annualized Cost to the Government

The estimated cost to carry out the data collection activities over the life of the project is \$ 515,374. This estimate includes the cost of recruitment, screening, conducting the interviews, analysis and reporting, as well as the total cost of the tokens of appreciation (\$40 per completed interview, for a total of \$4,000).

Exhibit A14.1: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, COR (GS-14 0.20 FTE)	\$22,901
	CDC, Contracting Officer (GS-13, 0.20 FTE)	\$19,950
	CDC, Contracting Officer (GS-12, 0.30 FTE)	\$21,570

	CDC, Contracting Officer (GS-12, 0.30 FTE)	\$21,570
	Subtotal, Direct Costs	\$85,991
Cooperative Agreement or Contract Costs	Contract Cost (ATLAS)	\$139,526
	Contract Cost (RSS)	\$289,857
	Subtotal, Cooperative Agreement or Contract Costs	\$429,383
	TOTAL COST TO THE GOVERNMENT	\$ 515,374

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

A final meeting to present the findings from the findings will be held in person at CDC in Atlanta at least two weeks before the end of the contract. The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Project Time Schedule

Activity	Time Schedule
Data collection tools, sampling and data pans, study protocol development	2-3 months before OMB approval
Recruitment	1 month after OMB approval
Data Collection	2-3 months after OMB approval
Data analysis finalized and report drafted	4 months after OMB approval
Final data set and final report submitted to CDC	5 months after OMB approval

16.1 Tabulation

Tabulation will include descriptive characteristics of study respondents collected in the first part of the interview (e.g., demographics, city, place in the treatment cascade, type of treatment center).

16.2 Publication

Rather than providing a traditional final report, CDC has requested that the final report consists of multiple manuscript documents that will be ready or near-ready for submission for publication. The final manuscripts will be submitted October 14, 2014. In addition, a PowerPoint presentation describing results and manuscript production would be produced to describe the findings. A final data set will also be provided. At the same time, in addressing a new and untested method of presenting findings it is expected that members of contractor project staff will need to work closely together to develop expectations for the number and draft-to-final quality each manuscript and presentation material achieves by the end of the contract period.

We anticipate that multiple manuscripts will be published in peer reviewed journals, presented at national conferences, and provided on conference websites. Links to these publications will be available through the CDC website.

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

We do not seek approval to eliminate the expiration date.

18. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exemptions to the certification.