“Community-Based Organization Outcome Monitoring Projects for CBO HIV Prevention Services Clients”

OMB #0920-NEW

Section A: Supporting Statement

March 14, 2017

CONTACT

Renee Stein, Ph.D.

Centers for Disease Control and Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Division of HIV/AIDS Prevention

Program Evaluation Branch

Phone: (404)639-3517

Fax: (404)639-0929

E-mail: rstein1@cdc.gov

**Table of Contents**

**Section**

1. **Justification**
2. Circumstances Making the Collection of Information

Necessary

1. Purpose and Use of Information Collection
2. Use of Improved Information Technology and Burden Reduction
3. Efforts to Identify Duplication and Use of Similar

Information

1. Impact on Small Businesses or Other Small Entities
2. Consequences of Collecting the Information Less Frequently
3. Special Circumstances Relating to the Guidelines of 5 CFR

1320.5

1. Comments in Response to the Federal Register Notice and

Efforts to Consult Outside the Agency

1. Explanation of Any Payment or Gift to Respondents
2. Protection of the Privacy and Confidentiality of Information Provided by Respondents
3. Institutional Review Board (IRB) and Justification for Sensitive Questions
4. Estimates of Annualized Burden Hours and Costs
5. Estimates of Other Total Annual Cost Burden to Respondents

and Record Keepers

1. Annualized Cost to the Government
2. Explanation for Program Changes or Adjustments
3. Plans for Tabulation and Publication and Project Time

Schedule

1. Reason(s) Display of OMB Expiration Date is Inappropriate
2. Expectations to Certification for Paperwork Reduction Act

Submissions

**Exhibits**

Exhibit 12.A Estimated Annualized Burden Hours

Exhibit 12.B Estimated Annualized Burden Costs

Exhibit 14.A Estimated Cost to the Government

Exhibit 16.A Project Time Schedule

**List of Attachments**

Attachment 1 Authorizing Legislation

Section 301 of the Public Health Service Act

Attachment 2 60-Day Federal Register Notice

Attachment 3 Eligibility Screener Forms

3a. Participant Interview Eligibility Screener Category 1

3b. Participant Interview Eligibility Screener Category 2

3c. Focus Group Eligibility Screener Category 1

3d. Focus Group Eligibility Screener Category 2

Attachment 4 Participation Agreement Forms

4a. Participant Interview Consent Category 1

4b. Participant Interview Consent Category 2

4c. Focus Group Consent Category 1

4d. Focus Group Consent Category 2

4e. Staff Interview Consent Category 1

4f. Staff Interview Consent Category 2

Attachment 5 Data Collection Forms

5a. Participant Interview – Category 1 Baseline

5b. Participant Interview – Category 2 Baseline

5c. Participant Interview – Category 1 Follow-Ups

5d. Participant Interview – Category 2 Follow-Ups

5e. Staff Interview Script Category 1

5f. Staff Interview Script Category 2

5g. Focus Group Script Category 1

5h. Focus Group Script Category 2

5i. Pre-Focus Group Questionnaire Category 1

5j. Pre-Focus Group Questionnaire Category 2

5k. Data Submission Form

5l. Medical Record Abstraction

5m. CBO-HPS Referrals

* **Goal of the study:** CDC funds community-based organizations (CBOs) to test and link or re-engage HIV-positive persons to medical care, and refer or provide HIV-positive persons and high-risk HIV-negative persons with HIV prevention and support services. The goal of this project is to conduct enhanced outcome monitoring of clients receiving CBO Health Prevention Services (CBO-HPS) over time to increase understanding of HIV prevention and support services they receive, the outcomes of these services, and successes and challenges related to service provision and utilization.
* **Intended use of the resulting data:** Inform efforts to reduce HIV infections, increase access to care, and improve health outcomes for clients receiving HIV prevention services at CBO-HPS CBOs. Also, to report data back to CBO-HPS CBOs and Project Officers during the CBO-HPS project period so that program improvements can be made.
* **Methods to be used to collect:** Structuredinterviews and record review with HIV-positive and high-risk HIV-negative clients at CBOs funded by CBO-HPS about demographics, HIV-related risk behaviors, HIV prevention and support services received, service outcomes, and experiences with services over time; staff interviews about strategies for and barriers to recruiting and engaging clients in HIV prevention and support services; and focus groups with clients who are receiving HIV prevention services at CBOs.
* **The subpopulation to be studied:** To be enrolled in CBO-HPS Category 1, participants must be receiving CBO-HPS, have received an HIV-positive test result, and have been provided a CBO-HPS referral to HIV medical care. To be enrolled Category 2, participants must be receiving CBO-HPS and must have received an HIV-negative result.
* **How data will be analyzed:** Statistical analysis of quantitative data. Qualitative thematic coding of staff interviews and focus group transcripts.

**A. Justification**

**1. Circumstances Making the Collection of Information**

**Necessary**

The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection called “Community-based Organization Outcome Monitoring Projects for CBO HIV Prevention Services Clients” for 3 years.

Background

CDC estimated in 2011 that 1.2 million persons were living with human immunodeficiency virus (HIV) infection in the United States, of whom 14% had undiagnosed infection (1). Each year 50,000 new persons become HIV infected, which has remained relatively stable since the mid-1990s.

CDC and its partners are pursuing a high-impact prevention (HIP) approach to advance the goals of the National HIV/AIDS Strategy for the United States: Updated to 2020 (Updated NHAS). These goals include reducing new HIV infections, increasing access to care and improving health outcomes among persons living with HIV, and reducing HIV-related disparities. The HIP approach prioritizes HIV prevention, testing, and support services for persons at greatest risk for HIV; prioritizing linkage to care within 30 days, and retention in care for people living with HIV; and directing these efforts to populations with the highest HIV burden. Yet in 2011, less than half (40%) of those diagnosed with HIV were engaged in HIV medical care, and only 30% achieved viral suppression (1). Furthermore, a new study found that 91.5% of new HIV infections are attributable to people with HIV not in medical care (2) – further underscoring the importance of early diagnosis and ongoing care and treatment.

For people who are HIV-negative, factors such as homelessness, substance addiction, and mental illness can put them at increased risk for HIV. Identifying these persons through HIV testing, and providing them with HIV prevention and support services (e.g., Pre-exposure prophylaxis (PrEP), non-occupational post-exposure prophylaxis (nPEP), screening and treatment for STDs) can avert new infections, thus reducing overall HIV incidence in the population.

CBOs play an essential role in reaching persons at high risk of transmitting and acquiring HIV infection. Through CBO Health Prevention Services (CBO-HPS), CDC funds 90 CBOs to provide comprehensive HIV prevention services to HIV-positive persons and high-risk HIV-negative persons. However, the CBO-HPS awardees are not required to monitor or report on critical outcomes such as whether HIV-positive persons who are linked to HIV medical care were retained in HIV medical care, prescribed antiretroviral treatment (ART), adhered to ART, and were virally suppressed and whether high-risk HIV-negative persons who were referred to PrEP initiated its use. Also, CBO-HPS CBOs are not required to collect and report data about clients’ perceived barriers to accessing HIV prevention services.

These projects will fund a subset of CBO-HPS awardees to collect and report data to CDC about the utilization and outcomes of the HIV prevention and support services. This will increase understanding of HIV prevention and support services received by CBO-HPS clients, the outcomes of these services, and successes and challenges related to service provision and utilization. Awardees will collect and report data that are aligned with the updated NHAS indicators. These projects will help address the updated NHAS’s call for developing improved mechanisms for monitoring and reporting results of efforts to reduce new HIV infections and improve health outcomes to chart progress over time at both the local and national levels.

Information will be collected through CBO staff-facilitated interviews with project participants and review of their medical records, interviews with CBO-HPS CBO staff members conducted by CDC, and focus groups with project participants administered by each CBO. The evaluation will involve quantitative and qualitative data collection and will evaluate self-reported data about demographics, HIV-related risk behaviors, HIV prevention and support services received, service outcomes, and experiences with services over time as well as a chart review for referrals and medical record abstraction for medication adherence and viral load values.

This project will support awards for 15-18 CBOs funded by CBO-HPS to conduct enhanced outcome monitoring of CBO-HPS clients over time under two funding categories: Category 1- HIV-positive clients and Category 2- high-risk HIV-negative clients.

For Category 1, self-reported client level data will be collected at baseline, 3, 6, 9 and 15 months. For Category 2, self-reported client level data will be collected at baseline, 3, 6, and 9 months. The baseline and follow-up surveys will collect demographic information, HIV-related risk behaviors, HIV prevention and support services received, service outcomes, experiences with services over time. See **Attachments 5a-5d** for baseline and follow-up surveys.

Up to two focus groups with clients who are receiving CBO-HPS services (**Attachments 5g-5h**) will collect information about clients’ attitudes about and experiences with HIV prevention and support services including needs and perceived barriers. This will include a pre-focus group questionnaire to collect demographic information.

Up to two interviews with CBO-HPS staff (**attachments 5e-5j**) will include information about strategies for and barriers to recruiting and engaging CBO-HPS clients in HIV prevention and support services.

This proposed information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241) to “…cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man…”. (**Attachment 1**)

**2. Purpose and Use of Information Collection**

The purpose of this project is to collect data to monitor critical HIV prevention service outcomes of CBO-HPS clients over time. Category 1 (for HIV-positive clients) will monitor outcomes over 3 years and Category 2 (for HIV-negative clients) will monitor outcomes over 2 years. These data will increase understanding of a) HIV prevention and support services received by CBO-HPS clients, b) the outcomes of these services, c) and successes and challenges related to service provision and utilization. Initial CBO-OMP findings will be reported back regularly to CBO-HPS grantees to foster ongoing programmatic improvement. Ultimately, these data will improve performance of CBO-HPS CBOs and contribute to reducing HIV infections, increasing access to care, and improving health outcomes for clients. If not collected, one possible negative consequence is not monitoring the critical outcomes of CBO clients over time and thus not being able to improve the services they need.

**3. Use of Improved Information Technology and Burden Reduction**

The “CBO-OMP Cat 1 Participant Interview” (**Attachment 5a**), “CBO-OMP Cat 2 Participant Interview” (**Attachment 5b**), “CBO-OMP Cat 1 Participant Interview Follow-ups” **(see Attachment 5c),** “CBO-OMP Cat 2 Participant Interview Follow-ups” (**Attachment 5d**) will be administered to participants by a CBO-OMP staff member. Surveys will be completed in private or semi-private areas as a measure to ensure participant privacy. Upon survey completion, agency staff will enter the survey data to a computer, encrypt the data file and submit the file to CDC via the Secure Date Network (SDN) monthly.

**4. Efforts to Identify Duplication and Use of Similar Information**

CBO-OMP grantees will monitor the outcomes of clients at CBOs funded under CBO-HPS that are not monitored through the CBO-HPS evaluation (i.e., National HIV Prevention Monitoring and Evaluation (NHM&E), OMB 0920-0696 exp. 2/28/2019). NHM&E data currently collects process monitoring data and can answer questions like which populations are HIV tests reaching, how many HIV positive persons are identified, and how many referrals to services are provided. To understand the outcomes of CBO-HPS and the impact that the program has on clients, and ultimately the larger community, we must monitor critical outcomes over time of HIV-positive clients who are not in care and high-risk HIV-negative clients. We need to understand more about the client’s perspective on accessing continuum of care services and on PrEP usage. We also need to have in-depth knowledge of strategies that CBOs are using to implement these services and how they change over time. This project will allow us to answer questions such as: (a) Are HIV-positive clients who are not in HIV medical care and referred to care through CBO-HPS (1) linked to or re-engaged in care within 30 days, (2) retained in HIV medical care, (3) using ART, and (4) virally suppressed? Why or why not? And (b) which high-risk HIV-negative clients are initiating PrEP and what are their patterns of use over time? How are PrEP education and referrals being implemented in real-world settings such as CDC-funded CBOs? What barriers do clients face in accessing PrEP? What factors contribute to starting and stopping PrEP and PrEP adherence? There are no other federal collections that duplicate the data collection tools and methods included in this request.

1. **Impact on Small Businesses or Other Small Entities**

This data collection will not involve small businesses.

1. **Consequences of Collecting the Information Less Frequently**

For Category 1, the follow-up surveys will be completed at 3, 6, 9, and 15 months following baseline. For Category 2, the follow-up surveys will be completed at 3, 6, and 9 months following baseline. The completion of the baseline and follow-up surveys is necessary to determine the outcomes of the HIV prevention services they receive. Collecting information at follow up allows CDC to evaluate HIV prevention services outcomes over time. Category 1 includes an additional follow-up interview because a longer period of time is necessary to accurately monitor retention to HIV medical care and viral suppression for HIV-positive persons.

Staff interviews are necessary to inform future strategies for recruiting clients, linking them to, re-engaging them in, and retaining them in HIV medical care, referring them to HIV prevention and support services (including PrEP), tailoring service provision to clients' needs, and identifying and addressing barriers to retaining clients in prevention services over time. Focus groups will provide context to better understand themes identified through client questionnaires and CBO staff interviews.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A 60-day federal register notice to solicit public comments was published in the Federal Register on 05/04/2016, Vol. 81, Number 86, Pages 26795-26797 (**Attachment 2**). There were no public comments received.

B CDC staff consulted with a statistical consultant, Dr. Weston Williams who we regularly work with. He has provided input in project design and analysis for previous CBO outcome monitoring projects.

**9.   Explanation of Any Payment or Gift to Respondents**

All project participants will be offered a token of appreciation depending upon the practices at the funded agencies. Tokens of appreciation will be in the form of gift cards valued at $25 and will be offered for participation in each of the following activities: the focus groups, baseline interview, and at each of the 3 month, 6 month, 9 month, and 15 month follow-up interviews.

The primary goal of the project is to conduct enhanced outcome monitoring of clients receiving CBO-HPS services over time to increase understanding of HIV prevention and support services they receive, the outcomes of these services, and successes and challenges related to service provision and utilization. For Category 1, it will be very challenging to recruit and retain 20 HIV-positive persons at each CBO to participate in 5 interviews over a 15-month period. Similarly for Category 2, it will be difficult to recruit and retain 210 high-risk HIV-negative persons at each CBO to participate in 4 interviews over a 9-month period. Many of these people will have characteristics that make them more difficult to enroll and retain such as unstable housing, substance abuse, and poverty.

The need for and amount of the remuneration is based, in part, on the fact that other, similar projects that ask HIV risk behavior questions in many metropolitan statistical areas offer similar tokens of appreciation. Thus, the proposed project would be competing with local evaluation projects that do offer remuneration. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which remuneration is the norm (Thiede 2009; MacKellar 2005)

Remuneration has been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 3/31/2017) and WILLOW (OMB 0920-0896, exp. 7/31/2015), both of which ask questions similar to those included in the proposed evaluation and have a similar length of time for completing the participant interview. In both of these other projects tokens of appreciation were used to help increase participation rates; participants were offered approximately $25 as a token of appreciation. Other studies have also found that incentives modestly improve response rates (Shaw et al. 2001).

The interview also contains highly sensitive questions regarding sexual history, experience of stigma and discrimination, and income. Providing incentives to respondents will be critical to achieving acceptable response rates in this hard-to-find population as demonstrated in the survey literature (Kulka 1995). A central objective of the proposed data collection is to identify the successes and challenges of keeping HIV-positive clients retained in HIV medical care over time.

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

The CDC NCHHSTP Coordinator has determined that the Privacy Act does not apply to this information collection. Respondents will be told that all individually identifiable information collected by the implementing agencies will not be submitted to CDC. A master list of assigned Client IDs with client names will be stored in a locked file cabinet and is intended for agency use only and will not be submitted to CDC. Participant names will not be recorded on any other data collection document and will not be stored on any device or laptop.

Project data will be stored and maintained in a secure area at all times at each agency in a locked file cabinet in the office of the project’s coordinator. All electronic data will be password protected and accessible only to project staff and direct supervisors. Data will be stored on network drives which are regularly backed up by staff.

Participation in this project is strictly voluntary. The consent process will be implemented according to the local/state policies of the funded agencies. Consent forms are provided in Attachment 4. The consent process for CBO-OMP involves the agency staff providing an overview of the project that includes a description of the benefits of as well as the risks and discomforts to participation as well as the protections for the respondent’s privacy. Participants must sign the consent form prior to enrolling into the project.

Participation in this CBO-OMP is strictly voluntary. The consent form clearly indicates that participation is voluntary and that there are no mandatory requirements, beyond eligibility, for participating in the project. Respondents are also informed that they may withdraw from the project at any time.

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

**IRB Approval**

This data collection has been determined to be not research involving human subjects. Therefore, IRB approval is not required.

**Sensitive Questions**

The project asks CBO-OMP participants questions that are of a sensitive nature. By nature of this project, participants are individuals who are HIV-positive and through self-report are identified as being at high risk for HIV transmission. This request covers the collection of HIV/STD behavioral risk data. Thus, participants will be asked to report on sensitive and private matters pertaining to their sexual practices and substance use. Some of the questions will ask about involvement in illegal activities (e.g., use of illegal substances, having sex in exchange for drugs or money) and about past HIV and STD diagnoses. This information may be considered by some participants to be highly sensitive in nature. Because collection of these data will be used to provide improved HIV prevention services to HIV-positive and high-risk HIV-negative negative persons, to enhance HIV prevention programs at the local level, specific information about client demographics and client risk profiles is essential to designing appropriate interventions and programs and to monitoring and evaluating these programs.

**12. Estimated Annualized Burden Hours and Costs**

**Category 1**

This information collection will occur over 33 months and will involve up to 15 CBOs. The population targeted by Category 1 are HIV-positive clients who are receiving CBO-HPS services and have been provided a CBO-HPS referral to HIV medical care. Data collection burden has been annualized.

Screening is conducted to determine if the respondent is eligible to participate in the participant interviews and is estimated to take 3 minutes to complete **(Attachment 3a)**. CBOs will screen approximately 15-20% more individuals than they will enroll in CBO-OMP. The 15 CBOs are required to enroll 10 HIV-positive persons each year (150 participants total each year). Therefore, we estimate that overall 175 HIV-positive persons will be screened each year.

Before each participant interview, CBO staff will collect their medical records **(Attachment 5l).** Specially, they will collect information about HIV-medical care visits, CD4 count and viral loads, and prescription to ART. It will take medical facility staff approximately 3 minutes to pull medical records for each of the 150 HIV-positive participants. This number is based on the amount of time the Medical Monitoring Project (OMB0920-0740 exp. 6/30/2018) allots facility staff to pull medical records.

In addition, before each participant interview, CBO staff will collect information about which CBO-HPS referrals the participant has received in the last three months before the baseline interview or since the last interview date for each follow-up interview **(Attachment 5m)**. It will take CBO-HPS approximately 3 minutes to send each participant’s referrals through the CBO-HPS to CBO-OMP program staff.

Participants will be administered a baseline interview **(Attachment 5a).** This interview is facilitated by a CBO staff member. The baseline interview is estimated to take 30 minutes to complete. It will take the CBO staff member approximately 10 minutes to enter the respondent’s interview data electronically, which is why their burden for participant interviews is 40 minutes for baseline.

Participants will be administered a follow-up interview at 3, 6, 9 and 15 months **(Attachment 5c)** after baseline. All surveys are facilitated by CBO staff members. The follow-up interviews are estimated to take 20 minutes. It will take the CBO staff member approximately 10 minutes to enter the respondent’s interview data electronically, which is why their burden for participant interviews is 30 minutes for each follow-up.

Screening is conducted to determine that a respondent is eligible to participate in the focus group and is estimated to take 3 minutes to complete **(Attachment 3c)**. The 15 CBOs are required to conduct one focus group per year and will screen approximately 10 persons at each CBO, resulting in 150 persons screened in total.

Participants in focus groups will complete a short questionnaire with demographic information **(Attachment 5i)**. This will last 2 minutes.

Each CBO will conduct one focus group per year **(Attachment 5g)**. Focus groups will be conducted with 6 to 8 participants who may also be participants in the participant interviews and will be facilitated by 2 CBO-OMP CBO staff members. The focus group will last 90 minutes.

Staff interviews are conducted by CDC and each interviews will last 2.5 hours **(Attachment 5e)**. Participants in the interviews will be 2 CBO-HPS program staff per CBO.

**Category 2**

This information collection will occur over 21 months. Category 2 will involve up to 3 CBOs. The population targeted by Category 2 are high-risk HIV-negative clients who are receiving CBO-HPS services. All data collection burden presented has been annualized.

Screening is conducted to determine if a respondent is eligible to participate in the participant interviews in this project and is estimated to take 3 minutes to complete **(Attachment 3b)**. CBOs will screen approximately 10-15% more individuals than they will enroll in CBO-OMP. The 3 CBOs will enroll 70 HIV-negative persons each year (total of 210 participants each year). We estimate that 225 persons will be screened each year.

Before each participant interview, CBO staff will collect their medical records **(Attachment 5l)**. Specially, they will collect information about medical care visits, and PrEP prescriptions. It will take medical facility staff approximately 3 minutes to pull medical records for each of the 210 participants. This number is based on the amount of time the Medical Monitoring Project (OMB 0920-0740 exp. 6/30/2018) allots facility staff to pull medical records.

In addition, before each participant interview, CBO staff will collect information about which CBO-HPS referrals the participant has received since they were referred to HIV medical care or since the last interview date **(Attachment 5m)**. It will take CBO-HPS approximately 3 minutes to send each client’s referrals through the CBO-HPS to CBO-OMP program staff.

Participants will be administered a baseline interview **(Attachment 5b).** This interview is facilitated by a CBO staff member. The baseline interview is estimated to take 30 minutes to complete. It will take the CBO staff member approximately 10 minutes to enter the respondent’s interview data electronically, which is why their burden for participant interviews is 40 minutes for baseline.

Participants will be administered a follow-up interview at 3, 6, and 9 months **(Attachment 5d)** after baseline. All surveys are facilitated by CBO staff members. The follow-up interviews are estimated to take 20 minutes. It will take the CBO staff member approximately 10 minutes to enter the respondent’s interview data electronically, which is why their burden for participant interviews is 30 minutes for each follow-up.

Screening is conducted to determine if a respondent is eligible to participate in a focus group **(Attachment 3d)** in this project and is estimated to take 3 minutes to complete. The three CBOs will screen approximately 10 persons each, resulting in 30 in total.

Participants in focus groups will complete a short questionnaire with demographic information **(Attachment 5j)**. This will last 2 minutes.

Each CBO will conduct a focus group yearly **(Attachment 5h)**. Focus groups will be conducted with 6 to 8 participants who may also be participants in the participant interviews and will be facilitated by 2 CBO-OMP CBO staff members. The focus group will last 90 minutes.

Staff interviews are conducted by CDC and each interviews will last 2.5 hours **(Attachment 5f)**. Participants in the interviews will be 2 CBO-HPS program staff per CBO.

All 18 CBO-OMP CBOs (15 in Category 1 and 3 in Category 2) funded to participate in this project will be required to submit data monthly **(Attachment 5k).** It is estimated that it will take 10 minutes per month. There is no cost to respondents other than their time.

The total annual burden hours is 1,266.

Exhibit 12.A Estimate of Annualized Burden Table

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Number of Respondents** | **Number of Responses per Respondent** | **Average Burden Response (Hours)** | **Total Burden (Hours)** |
| General public | Screener Participant Interview Category 1 (Attachment 3a) | 175 | 1 | 3/60 | 9 |
| Facility office staff | Medical records abstraction Category 1 (Attachment 5l) | 150 | 3 | 3/60 | 23 |
| CBO-HPS grantees | CBO-HPS Referrals Category 1 (Attachment 5m) | 150 | 3 | 3/60 | 23 |
| General public | Baseline Interview Category 1 (Attachment 5a) | 150 | 1 | 40/60 | 100 |
| General public | 3,6,9, and 15 Month Follow-up Interview Category 1 (Attachment 5c) | 150 | 4 | 30/60 | 300 |
| General public | Screener Focus Group Category 1 (Attachment 3c) | 150 | 1 | 3/60 | 8 |
| General Public | Focus Group Questionnaire Category 1 (Attachment 5i) | 90 | 1 | 2/60 | 3 |
| General public | Focus Group Category 1 (Attachment 5g) | 90 | 1 | 1.5 | 135 |
| CBO-HPS grantees | Staff Interview Category 1 (Attachment 5e) | 30 | 1 | 2.5 | 75 |
| CBO-OMP CBOs | Data submission Category 1 and 2 (Attachment 5k) | 18 | 12 | 10/60 | 36 |
| General public | Screener Participant Interview Category 2 (Attachment 3b) | 225 | 1 | 3/60 | 12 |
| Facility office staff | Medical records abstraction Category 2 (Attachment 5l) | 210 | 2 | 3/60 | 21 |
| CBO-HPS grantees | CBO-HPS Referrals Category 2 (Attachment 5m) | 210 | 2 | 3/60 | 21 |
| General public | Baseline Interview Category 2 (Attachment 5b) | 210 | 1 | 40/60 | 140 |
| General public | 3,6, and 9 Month Follow-up Interview Category 2 (Attachment 5d) | 210 | 3 | 30/60 | 315 |
| General Public | Screener Focus group Category 2 (Attachment 3d) | 30 | 1 | 3/60 | 2 |
| General Public | Focus Group Questionnaire Category 2 (Attachment 5j) | 18 | 1 | 2/60 | 1 |
| General public | Focus Group Category 2 (Attachment 5h) | 18 | 1 | 1.5 | 27 |
| CBO-HPS grantees | Staff Interview Category 2 (Attachment 5f) | 6 | 1 | 2.5 | 15 |
| Total |  |  |  |  | 1266 |

Exhibit 12.B Estimated Annualized Burden Costs

|  |  |  |  |
| --- | --- | --- | --- |
| **Respondent** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Cost** |
| Screener participant interview- General population Category 1 | 9 | $23.23 | $209.07 |
| Facility office staff pulling medical records Category 1 | 23 | $23.23 | $534.29 |
| CBO-HPS grantees sharing CBO-OMP participant referrals Category 1 | 23 | $23.23 | $534.29 |
| Baseline Survey – General population Category 1 | 100 | $23.23 | $2,323.00 |
| 3,6,9, and 15-Month Follow-up Survey - General Population Category 1 | 300 | $23.23 | $6,969.00 |
| Screener focus group General population Category 1 | 8 | $23.23 | $185.84 |
| Focus Groups Questionnaire– General population Category 1 | 3 | $23.23 | $69.69 |
| Focus Groups– General population Category 1 | 135 | $23.23 | $3,136.05 |
| Staff Interview– CBO-HPS grantees Category 1 | 75 | $23.23 | $1,742.25 |
| Data Entry Category 1 and 2 | 36 | $23.23 | $836.28 |
| Screener participant interview- General population Category 2 | 12 | $23.23 | $278.76 |
| Facility office staff pulling medical records Category 2 | 21 | $23.23 | $487.83 |
| CBO-HPS grantees sharing CBO-OMP participant referrals Category 2 | 21 | $23.23 | $487.83 |
| Baseline Survey – General population Category 2 | 140 | $23.23 | $3,252.20 |
| 3,6,and 9-Month Follow-up Survey - General Population Category 2 | 315 | $23.23 | $7,317.45 |
| Screener focus group General population Category 2 | 2 | $23.23 | $46.46 |
| Focus Groups Questionnaire– General population Category 2 | 1 | $23.23 | $23.23 |
| Focus Groups– General population Category 2 | 27 | $23.23 | $627.21 |
| Staff Interview– CBO-HPS grantees Category 2 | 15 | $23.23 | $348.45 |
| Total |  |  | $29,409.18 |

B. Annualized cost to respondents for the burden hours is provided in Exhibit 12.B. The estimate of hourly wages were obtained from the United States Department of Labor’s Bureau of Labor Statistics and is based on the May 2015 National Occupational Employment and Wage Estimates for all occupations (http://www.bls.gov/oes/current/oes\_nat.htm ).

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

There are no costs to respondents other than their time.

**14. Annualized Cost to the Federal Government**

The annualized cost to the government is $2,134,519.95. The project is funded to measure the outcomes of clients at CBOs funded through a Cooperative Agreement #CDC-RFA-PS15-1502 to 90 CBOs (CBO-HPS) for three years. The project will involve participation of two CDC project officers (GS-13 level) and a CDC Co-Principal Investigator (GS-14 level) who will be responsible for project design, project oversight, and analysis and dissemination of the results. The CDC project officer will provide remote and onsite technical assistance to the agencies implementing the data collection. Two contractors (a project coordinator and a data manager) will also work on the project. An estimated cost per individual activity is listed below.

Exhibit 14.A Estimate of Annualized Costs to the Federal Government

| **Expense Type** | **Expense Explanation** | **Annual Costs (dollars)** |
| --- | --- | --- |
| Direct Costs to the Federal Government | CDC Project Officer (Category 1)  (Health Scientist,GS-13,.25 FTE) | $21,804.75 |
|  | CDC Project Officer (Category 2)  (Health Scientist,GS-13,.25 FTE) | $21,804.75 |
|  | CDC Co-Principal Investigator (GS-14, .05 FTE) | $5,217.45 |
| Operational | Travel – two trips for Project Officer | $22,500 |
|  | Subtotal, Direct Costs to the Government | $71,326.95 |
| Contractor and Other Expenses | Project Coordinator (Karna, .75) | $105,241 |
|  | Data Manager (Karna, .25) | $37,952 |
|  | Category 1 | $1,350,000 |
|  | Category 2 | $570,000 |
|  | Subtotal, Contracted and other expenses | $2,063,193.00 |
|  | TOTAL COST TO THE GOVERNMENT | $2,134,519.95 |

Salary estimates were obtained from the United States Public Health Service Commissioned Corps Website (<http://dcp.psc.gov/>) and the OPM salary scale (<http://www.opm.gov/>).

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Exhibit 16.A Project Time Schedule

All data collected by CBO-OMP staff is owned and retained by the Centers for Disease Control and Prevention.

|  |  |
| --- | --- |
| **Activity** | **Time Schedule** |
| Data collection begins | January 1st, 2017. (within 1 month of OMB approval) |
| Data submission to CDC | Monthly |
| Initial data analysis | Within 6 months of OMB approval |
| Evaluation updates to Prevention Program Branch, CBO-HPS Project Officers, and CBO-OMP grantees | Bi-annually |
| Data collection ends | 33 months after OMB approval |
| Final Analysis begins | 33 months after OMB approval |
| Dissemination of results | 40 months after OMB approval |

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

No exception is requested.

**18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h) (1)-(10)**

No exception is requested.

References

CDC Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV — United States, 2011, November 28, 2014 /63(47); 1113-1117, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm634 7a5.htm

Kulka, R.A. (1994), “The use of incentives to survey ‘hard-to-reach’ respondents: A brief review of empirical research and current practice.” Paper presented at the COPAFs Seminar on New Directions in Statistical Methodology, Bethesda MD. May.

MacKellar, D. A., Valleroy, L. A., Secura, G. M., Behel, S., Bingham, T., Celentano,D.D.,…Young Men’s Survey Study Group. (2005).Unrecognized HIV infection, risk behaviors, and perceptions of risk among young men who have sex with men: Opportunities for advancing HIV prevention in the third decade of HIV/AIDS. Journal of Acquired Immune Deficiency Syndromes, 38(5), 603–614.

Shaw MJ, Beebe TJ, Jensen HL, Adlis. SA: The use of monetary incentives in a community survey: Impact on response rates, data quality, and cost. Heal Serv Res. 2001, 35 (6): 1339-1346.

Skarbinski J, Rosenberg E, Paz-Bailey G, Hall HI, Rose CE, Viall AH, Fagan JL, Lansky A, Mermin JH. Human Immunodeficiency Virus Transmission at Each Step of the Care Continuum in the United States. JAMA Internal Medicine, 2015[Thiede et al., 2009](http://www.sciencedirect.com/science/article/pii/S0376871616000600#bib0200) H.

Thiede, R.A. Jenkins, J.W. Carey, R. Hutcheson, K.K. Thomas, R.D. Stall, E. White, I. Allen, R. Mejia, M.R. Golden Determinants of recent HIV infection among Seattle-area men who have sex with men Am. J. Public Health, 99 (Suppl. 1) (2009), pp. S157–S164