**Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD)**

**OMB No. 0920-****1402 OMB Expiration 05.31.2026**

**Supporting Statement A**

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* **Goal of the study**: The goal of the project is to assess individual and systems level factors that are likely to contribute to barriers and gaps in testing and prevention that played a part in having persons receiving either an early (stage 0) or late (stage 3) HIV diagnosis.
* **Intended use of the resulting data:** The data obtained through this enhanced surveillance activity will identify actionable missed opportunities for early diagnosis and prevention, thus informing allocation of resources, development and prioritization of interventions, and evidence-based local and national decisions to improve HIV testing and address prevention gaps.
* **Methods to be used to collect data**: Interviewer-administered phone surveys and self-administered web-based surveys of persons with recently diagnosed HIV at stage 0 (early) or stage 3 (late)and phone-based interviewer-administered in-depth interviews (IDI).
* **The subpopulation to be studied**: Adult persons who received an HIV diagnosis at stage 0 (i.e., early infection) or who received a diagnosis at stage 3 (i.e., late infection or AIDS) in the preceding 12 months from the time of data collection.
* **How data will be analyzed:** Survey data will be analyzed using SAS software or other appropriate statistical packages. Univariate and bivariate statistics and multivariable regression methods will address the project’s objectives. A qualitative thematic analysis will be done with the IDI transcripts.

**Supporting Statement**

**A. Justification**

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV Prevention (DHP) request a revision of the approved "Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses project” (SHIELD) (OMB#0920-1402; exp. 5/31/26).

CDC awarded cooperative agreements to four Health Departments through a Notice of Funding Opportunity, PS22-2211, to conduct recruitment of participants into the study and a Contract to conduct centralized interviewing. This project aims to enhance the ability of the CDC to provide insight into individual and system-level barriers that prevent people from fully realizing the benefits of current HIV prevention and testing interventions. Early and late diagnoses present opportunities to examine failures of HIV prevention and testing services to reach those who most need them. Enhanced surveillance of people with early and late diagnoses is needed to identify actionable missed opportunities for early diagnosis and prevention, thus informing the allocation of resources, development, prioritization of interventions, and evidence-based local and national decisions to improve HIV testing and address prevention gaps. Findings will improve services at the local level to prevent new HIV diagnoses and get people diagnosed and on treatment sooner.

Background, Need and Circumstances Motivating the Request

National HIV Surveillance System (NHSS) data indicate that 36,940 adolescents and adults received an HIV diagnosis in the United States and dependent areas in 2019. During 2015-2019, the overall rate of annual diagnoses decreased only slightly, from 12.4 to 11.1 per 100,000 [1, reference in **Attachment 3**]. Although not every jurisdiction reports complete laboratory data needed to identify the stage of infection, data from the majority of jurisdictions show that many of these cases were classified as stage 0 (6.9%) or stage 3 (21.5%) infection (i.e., cases diagnosed in early infection or late infection, respectively) [2]. Early and late diagnoses represent recent failures in prevention and testing systems, respectively, and opportunities to understand needed improvements in these systems.

The NHSS would classify HIV infections as stage 0 if the first positive HIV test were within six months of a negative HIV test [3]. Persons who received a diagnosis at stage 0 (i.e., early diagnosis) could access HIV testing shortly after infection yet could not benefit from biomedical and behavioral interventions to prevent HIV infection.

The federal Ending the HIV Epidemic in the U.S. (EHE) initiative prioritizes the provision of HIV preexposure prophylaxis (PrEP), syringe services programs, treatment as prevention efforts, and other proven interventions — as part of the Prevent pillar of the EHE initiative — to prevent new HIV infections [4].

HIV infections are classified as stage 3 (AIDS) by the presence of an AIDS-defining opportunistic infection or by the lowest CD4 lymphocyte test result [3]. Persons with stage 3 infection at the time of their initial HIV diagnosis (i.e., late diagnosis) did not benefit from timely receipt of testing or HIV prevention interventions. They were likely unaware of their infection for a substantial length of time. Nationally, an estimated 13.3% of persons with HIV are unaware of their infection [5], contributing to an estimated 40% of all ongoing transmission [6]. Increasing early diagnosis is a crucial pillar of efforts to end HIV in the United States [4].

Given the continued occurrence of HIV infections in the United States, the barriers and gaps associated with low uptake of HIV testing and prevention services must be addressed to reduce new infections and facilitate timely diagnosis and treatment. Individual- and systems-level factors likely contribute to barriers and gaps in testing and prevention.

This proposed information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241)**.**

## Purpose and Use of Information Collection

The purpose of this information collection is to improve understanding of barriers and gaps associated with new infection and late diagnosis in the era of multiple testing modalities and prevention options such as PrEP. These enhanced surveillance activities will identify actionable missed opportunities for early diagnosis and prevention, thus informing allocation of resources, development, and prioritization of interventions, and evidence-based local and national decisions to improve HIV testing and address prevention gaps. If these data are not collected, the CDC’s ability to support HIV prevention and testing programs responsive to the needs of priority populations will be hindered.

This enhanced surveillance project will be conducted in collaboration with four US health departments. Each health department will use their local Enhanced HIV/AIDS Reporting System (eHARS) data to generate and update lists of all persons who received a stage 0 or stage 3 diagnosis in the past 12 months, using a census approach. The number of eligible persons will vary by jurisdiction based on the number of new HIV diagnoses.

Of all new diagnoses identified in 2019 in these four health departments, 595 received a diagnosis at stage 0, and 1,496 received a diagnosis at stage 3. It is anticipated that these annual sample sizes will remain comparable during the years of data collection.

Health departments will attempt to locate, contact, and recruit all persons on the eligible case list. During contact with persons on the eligible case list, the recipient will facilitate access to referrals for ancillary services and care linkage and retention.

The eligibility criteria for participation in surveys include: 18 years of age and older; diagnosed in either stage 0 or stage 3 as defined by CDC; diagnosed within the past 12 months; lived in the funded project area at the time of HIV diagnosis; able to read and understand English or Spanish. During recruitment, health department staff will confirm eligibility criteria using a Recruitment Script (**Attachment 4A and 4B**). Eligible and interested persons will be invited for a phone or web-based interview in English or Spanish, which will take approximately 50 minutes to complete the quantitative survey (**Attachment 6A and 6B**)and 90 minutes to complete the qualitative (**Attachment 6C and 6D**). The phone-based interview will be conducted through a CDC Contractor.

The information collected will be used to describe individual and system factors associated with new infections and late diagnosis, such as barriers and facilitators to HIV testing and HIV prevention strategies, including preexposure prophylaxis (PrEP), with the goal of prioritizing interventions and efforts to prevent infections and facilitate early diagnosis and linkage to care.

This project is intended to develop a new, enhanced surveillance activity with the potential for regular and ongoing monitoring of the frequency and distribution of testing and prevention failures and other relevant characteristics of persons with a recent diagnosis at stage 0 or stage 3.

## Use of Improved Information Technology and Burden Reduction

Information will be collected using computer-assisted telephone interviews (CATI) or computer-assisted web interviews (CAWI). The web-based modality will be offered to improve flexibility and reduce the burden of the participant completing the survey during a fixed appointment. Data are collected electronically to minimize the burden on participants and interviewers. By entering data directly into the web-based survey system in both CATI and CAWI modalities, the efficiency of data collection is improved compared to using paper and then transferring that data into a computer database. These modalities will also enable skip patterns to further reduce the burden to participants.

## Efforts to Identify Duplication and Use of Similar Information

We reviewed currently funded programs and Reginfo.gov and did not identify potential areas of duplication. We are not aware of any department or agency that collects data on key information on barriers and gaps in services experienced by those diagnosed with early and late-stage HIV infection nationally, in conjunction with local and state health departments. The in-depth interviews will allow for additional exploration of specific themes and topics from the survey that requires further expansion to understand how to best address gaps and barriers to ending the HIV Epidemic.

Currently, the CDC conducts the Medical Monitoring Project (MMP) (OMB # 0920-0770), which collects behavioral and clinical data on a nationally representative sample of persons living with a diagnosis of HIV infection through interviews and medical record abstraction; however, MMP does not oversample persons with a recent diagnosis or those with an early or late HIV diagnosis, which does not allow CDC to make inferences specific to these groups. Furthermore, MMP does not routinely collect qualitative data to delve deeper into barriers and facilitators of early and late HIV diagnoses.

## Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

## Consequences of Collecting the Information Less Frequently

The proposed data collection involves one-time data collection from respondents. Each respondent will respond to this information collection only once. There are no legal obstacles to reducing the burden.

The information collected will provide quantitative and qualitative data needed to understand and describe individual- and system-level factors associated with new infection and late diagnosis, such as barriers and facilitators to HIV testing and HIV prevention services, including preexposure prophylaxis (PrEP), with the ultimate goal of prioritizing interventions and efforts to prevent infections and facilitate early diagnosis and linkage to care. If these data are not collected, the CDC’s ability to support HIV prevention and testing programs that are responsive to the needs of priority populations will be hindered.

## Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

At this time, we are not able to change the race and ethnicity questions in the SHIELD survey (**attachment 6A**) to match the new OMB standard (SPD-15) as it will cause undue burden, cost to the government, and substantial delay in the project.

The SHIELD survey has been implemented since July 2023 and will continue collecting data until July 2025 as one continuous cycle. We currently have nearly 10 months of data collected using the race and ethnicity questions that were approved in our original ICR. We need to continue collecting data until July 2025 using the same questions. Adopting the new standard at this time would certainly incur additional cost and most importantly delays, as we would need to have our contractor reprogram the survey, test it doing additional UATs and retrain the interviewers to conduct the survey via telephone. SHIELD is unique because we are recruiting a very vulnerable population who is hard to recruit, and therefore, we need all 24 months of data collection without interruption so we can obtain sufficient sample size. Any delay would hamper the ability of SHIELD to be effective at completing its goal of understanding new barriers to testing and prevention among those recently diagnosed with HIV.

Once this continuous cycle ends we would certainly adopt the new race/ethnicity standards for future cycles of SHIELD to be compliant before 2029.

About Attachment 6C, this is the in-depth interview (IDI) guide which does not have a demographics section as participants will be invited to do the SHIELD survey (**attachment 6A**) after they complete the IDI. Any demographic information that we have at this encounter would come from EHARS. Therefore, we will not add the new race/ethnicity standard here as we do not want to add burden to the participants by asking the same question twice and in different formats.

## 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 10/06/2023, Volume 88, Number 193, Page Number 69640 (**Attachment 2**). Public comments can be found in **Attachment 2a**. The Notice was titled “Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD)”and closed on 12/06/2023, with two comments. Neither of the comments required any additional actions or request.

In 2021, we consulted with leaders in the community who work directly with people with HIV in non-profit and human rights organizations, as well as a licensed marital and family therapist whose work combines mental and sexual health, as well as AIDS-related death and trauma.

To inform the refinement of the survey, in 2021, we consulted with two associate professors, one from Duke University and the other from the University at Buffalo. Both have extensive backgrounds in qualitative and mixed methods research, specifically in HIV prevention.

In addition, we received input and feedback on survey items from the Medical Monitoring Project (MMP) (OMB # 0920-0740) community and provider advisory boards in 2022. The advisory board members reviewed items from the survey to ensure the items were reflective of patient experiences.

We also partnered with researchers at Emory University to conduct 9 cognitive interviews in English to refine specific items from the survey. Some of the items included: barriers to testing for HIV, reasons for not taking PrEP, access to healthcare, experiences with discrimination/harassment, and certain types of risk behaviors such as binge drinking alcohol and condom use frequency. We also conducted 9 cognitive interviews in Spanish to assess the cultural appropriateness and cognition of specific items of the translated survey.

In 2022, upon award of the cooperative agreement, the survey instrument was shared with the four project areas, who reviewed it in consultation with their community partners and provided feedback and local questions.

External consultant’s name and contact information is included in **Attachment 8**.

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

Recruiting respondents with recently diagnosed HIV infection is central to the success of the proposed enhanced surveillance project. To promote recruitment and increase response rate a token of appreciation will be provided to respondents. For the proposed data collection, the respondent will receive a $50 token of appreciation for their participation for the quantitative survey and/or the qualitative in-depth interview (IDI) guide. Participants who complete the quantitative and qualitative components of the survey will be compensated $100. The amount of the token of appreciation is the same as previously approved for other HIV-related CDC data collection efforts, such as the National HIV Behavioral Surveillance (NHBS) (OMB 0920-0770, exp. 4/30/2026) and the MMP (OMB # 0920-0740, exp. 05/31/2024), which used a data collection instrument of similar length and complexity as the proposed information collection. In these other projects, tokens of appreciation were used to increase participation rates.

In addition, the amount is justified by the difficulties in recruiting persons who have been recently diagnosed with HIV infection and who might or might not be receiving medical care, in addition to the sensitive nature of the questions asked during the interview.

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 [7-9]. In addition, HIV has an inherent stigma associated, which makes it difficult to recruit respondents for research when compared to recruiting for other health issues [10]. In one study on research respondent recruitment in Hispanic/Latino communities, researchers noted that the stigma related to HIV/AIDS is a major barrier in subject recruitment for HIV/AIDS behavioral research [9]. Offering tokens of appreciation is considered necessary to recruit minorities and historically underrepresented groups. Barriers related to recruiting minorities include (1) lack of trust among minority communities towards the medical research process and research [11]; (2) a lack of competence among researchers to use culturally appropriate approaches for recruitment,[12]; and (3) reluctance to participate due to inconvenience and a lack of time [10].

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

A Privacy Act Checklist has been completed. The Privacy Act is not applicable because PII is not being collected under this CDC-funded activity (**Attachment 11 PIA**). This information collection is covered under the Privacy Act system of records notice (SORN) # 09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC”, which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

The Contractor will be responsible for collecting all survey data for this surveillance project. Sensitive information collected by the Contractor will not be linked to any other personally identifiable information (PII) and cannot be used to reveal the identity of any one person. No information that could directly identify an individual will be collected as part of the interview by the Contractor. The Contractor will generate a unique identification code (Participant ID) at the time of participant registration. Each Participant ID will include a health department-specific prefix, and the Participant ID shall not include PII (i.e., no date of birth, social security number, etc.). The Contractor will ensure Participant IDs are unique and not duplicated. This Participant ID will be used as a link between all processes (registration, scheduling, completion status, distribution of token of appreciation, etc.). Any contact information collected for the purposes of recruiting (i.e., name and telephone number) will only be accessed by local and state health departments. Health departments will be responsible for securely maintaining the link between the generated Participant ID and the health department’s record of each participant’s contact information.

The Contractor 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 study team. Terms of the CDC contract authorizing data collection require the Contractor to maintain the privacy of all information collected. CDC and the CDC contractor will not receive any respondent PII.

The NCHHSTP IT Security Information System Security Officer (ISSO), determined that this project does not involve a federal information system. The system is owned and operated by the Contractor. Federal Information Security Management Act of 2002 (FISMA) requirements are not applicable, and a System Security Plan is required prior to data processing for the contractor system.

This project is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 9**). The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever and endure even after the respondent’s death.

Confidentiality precautions approved for telephone interviewing are also applied to videoconference interviewing, which include ensuring that the participant and the interviewer each has a private location in which to conduct the interview. No audiovisual recordings will be made of the interviews obtained through telephone or videoconferencing. Videoconferencing may improve privacy by removing the need to mail project materials such as response cards to participants, as these can be shown to the participant during the videoconference. Additionally, project interviewers may only conduct videoconference interviews on desktop or laptop computers that have password protection, encryption, and controlled access via a secure network.

Contractor’s interviewers will complete confidentiality training and sign the statement indicating their understanding of security and confidentiality policies related to HIV surveillance data. Interviewers will also receive training from CDC staff on how to protect the security and confidentiality of the information collected.

The Assurance of Confidentiality will be enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance and the CDC Contractor will be subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of National HIV Surveillance System data (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf) and will be required to undergo security and confidentiality training.

Data collectors and data managers will undergo annual security and confidentiality training consistent with the guidelines set forth in the document “Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs” available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf). CDC’s Office of Grants Services will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, local area network [LAN] support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a “Agreement to Abide by Restrictions on Release of Data” (**Attachment 10**), and to update their confidentiality agreements on an annual basis. Contractors must sign a “Contractor’s Pledge of Confidentiality.” Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the “Agreement to Abide by Restrictions on Release of Data.”

Data collectors will obtain informed consent from all respondents prior to the interview. The informed consent process for respondents will be fulfilled by obtaining electronic consent by the respondent, or by having the interviewer sign a consent document attesting to the respondent’s verbal consent. An example model consent document is included as **Attachment 5A, 5B, 5C, and 5D.** Respondents will be told that they may decline to participate without penalty or, if they agree to participate, they may refuse to answer any question. Respondents will be informed that data collected from them for this project will be kept private and secure and that the data will be reported in aggregate format.

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

**IRB**

This project was determined by the National Center for HIV, Viral Hepatitis, STD and TB Prevention’s Office of the Associate Director for Science at the Centers for Disease Control and Prevention (CDC) to be a non-research, public health surveillance activity used for disease control program or policy purposes (**Attachment 7 - Approved Project Determination**). Because this project is non-research, the project is not required to be reviewed by a Federal institutional review board (IRB). Nonetheless, CDC investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality, and autonomy of participants. Participating health departments may obtain local IRB approval before data collection begins, if required in their jurisdiction. All applicable Federal and state privacy laws must be followed.

**Sensitive Questions**

This project will collect information on sensitive HIV risk and prevention behaviors. Question topics include sexual orientation, HIV testing history, barriers to testing services, experience with PrEP, barriers to accessing PrEP, substance and alcohol use, high-risk sexual behavior, experiences with health care providers and experiences within health care settings, access to mental health services, stigma, and stressful life events.

Understanding the slight possibility of an emotional response or anxiety on the part of the respondent, all interviewers will be trained to handle these potential adverse events and to provide respondents with state-specific hotlines for HIV and mental health care organizations as needed. We will inform all respondents that they may skip any question or stop participation for any reason.

Although the information requested from participants is highly sensitive, this project cannot achieve its goals without their collection. The collection of the data is used to understand barriers to engaging in protective behaviors, using HIV prevention services, and other services. The context in which questions are asked helps to overcome their potential sensitivity. Several steps will be taken to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

* + Nearly all survey questions allow for responses of “don’t know” or “Prefer not to respond.”
	+ The consent form clarifies how and by whom the information will be used, and that CDC sponsors the survey, and phone numbers will be provided if the respondent has questions about the survey.
	+ The survey is carefully organized to lead smoothly from one topic to another. Transitions are made clear to participants, and the need for the information is explained. Assurances about the privacy and confidentiality of the data are reiterated.
	+ The payment of a token of appreciation indicates to the respondent that the information is vital to the survey sponsors.

## 12. Estimates of Annualized Burden Hours and Costs

The estimated annualized burden hours for this revised data collection is **3,074** hours, increasing by 158 burden hours to include a new qualitative data collection activity; the burden hours for the original ICR will remain the same. Contact information has been updated in the approved Consent form (**Attachment 5a and 5b)**. Minor revisions have been made to the approved data collection instrument (quantitative survey) to improve clarity and administration **(Attachment 6a and 6b)**.

Four health departments will locate, contact, and recruit all persons with early (Stage 0) and late diagnosis (Stage 3) on the eligible case list generated from their local eHARS data for the proposed information collection. Although the number of eligible persons will vary by jurisdiction based on the number of new HIV diagnoses, we anticipate that up to 3,000 persons annually will be in the eligible case list. A recruitment script (**Attachment 4a and 4b**) will be used to confirm eligibility by assessing the respondent’s age, date of diagnosis, and stage of HIV at diagnosis. We estimate it will take 15 minutes to complete the recruitment screener. The same recruitment screener will be used for the survey and the qualitative interviews **(Attachment 4a and 4b)**.

***Qualitative Data Collection***

Approximately 2,500 persons will be recruited annually into the study, and of them, approximately 100 will be selected to participate in a qualitative data collection activity, that will take place prior to the quantitative data collection activity.

Persons selected for the qualitative data collection will undergo a consent process lasting 5 minutes (**Attachment 5c and 5d Model Consent for Qualitative Interview)** and complete a phone-based in-depth interview lasting approximately 90 minutes (**Attachment 6c and 6d In-depth Interview Guide**).

Once the participant completes the qualitative interview, they will be invited to participate in the quantitative data collection on a different date. See next paragraph for the process they will follow.

***Quantitative Data Collection***

Approximately 2,500 persons will be recruited annually into the study and undergo the consent process (**Attachment 5a and 5b**). The participant will take approximately 5 minutes to read the consent form. After providing consent, the participant will complete the survey (**Attachment 6a and 6b**) via CATI or CAWI. Completion of the survey is estimated to take 50 minutes.

**Exhibit A12.A: 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** |
| --- | --- | --- | --- | --- | --- |
| Potential Eligible Participant | Recruitment Script English (Att 4a) | 2,000 | 1 | 15/60 | 500 |
| Potential Eligible Participant | Recruitment Script Spanish (Att 4b) | 500 | 1 | 15/60 | 125 |
| Eligible Participant | Consent for quantitative survey – English (Att 5a) | 2,000 | 1 | 5/60 | 167 |
| Eligible Participant | Consent - Spanish (Att 5b) | 500 | 1 | 5/60 | 42 |
| Eligible Participant  | Survey – English (Att 6a) | 2,000 | 1 | 50/60 | 1,666 |
| Eligible Participant | Survey – Spanish (Att 6b) | 500 | 1 | 50/60 | 416 |
| Eligible Participant | Consent for qualitative interview– English (Att 5c) | 50 | 1 | 5/60 | 4 |
| Eligible Participant | Consent for qualitative interview - Spanish (Att 5d) | 50 | 1 | 5/60 | 4 |
| Eligible Participant  | In-depth Interview – English (Att 6c) | 50 | 1 | 90/60 | 75 |
| Eligible Participant | In-depth Interview – Spanish (Att 6d) | 50 | 1 | 90/60 | 75 |
| **Total** | **3,074** |

**A.12.B. Estimated Annualized Burden Costs**

The annualized costs to the respondents is estimated to be $91,480; details are provided in Exhibit A.12.B. The United States Department of Labor Statistics May 2022 <http://www.bls.gov/oes/current/oes_nat.htm> was used to estimate the hourly wage rate for the general public for this request. This cost represents the total burden hours to respondents multiplied by the average hourly wage rate for adults ($29.76).

Exhibit A.12.B. Estimated Annualized Burden Costs

| **Type of Respondent** | **Form Name** | **Total** **Burden****Hours** | **Hourly Wage Rate**  | **Total Respondent Costs**  |
| --- | --- | --- | --- | --- |
| Potential Eligible Participant | Recruitment Script - English  | 500 | $29.76 | $14,880 |
| Potential Eligible Participant | Recruitment Script - Spanish | 125 | $29.76 | $3,720 |
| Eligible Participant | Consent - English  | 167 | $29.76 | $4,969 |
| Eligible Participant | Consent - Spanish  | 42 | $29.76 | $1,249 |
| Eligible Participant  | Survey – English | 1,666 | $29.76 | $49,580 |
| Eligible Participant | Survey - Spanish | 416 | $29.76 | $12,380 |
| Eligible Participant | Consent - English  | 4 | $29.76 | $119 |
| Eligible Participant | Consent - Spanish  | 4 | $29.76 | $119 |
| Eligible Participant | In-depth Interview – English | 75 | $29.76 | $2,232 |
| Eligible Participant  | In-depth Interview - Spanish | 75 | $29.76 | $2,232 |
| Total |  |  |  | $91,480 |

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

There are no other costs to respondents associated with this proposed collection of information.

## 14. Annualized Cost to the Government

The annualized cost to the government is $2,370,027. The annualized cost is summarized in Exhibit A14.1

**Exhibit A14.1: Annualized Cost to the Government**

|  |  |  |
| --- | --- | --- |
| **Expense Type** | **Expense Explanation** | **Annual Costs** **(dollars)** |
| Direct Costs to the Federal Government | CDC– Personnel Epidemiologist-14 1 25% $38,250Epidemiologist-13 3 100% $388,416Epidemiologist-12 1 100% $108,886Support StaffProject Coordinator 1 100% $150,000 | $685,552 |
|  | Cooperative agreement funds to participating health departments  | $866,300 |
| Contractor and Other Expenses  | CDC Contractor for data collection  | $812,675 |
|  | Spanish language translation | $5,500 |
|  | TOTAL COST TO THE GOVERNMENT | $2,370,027 |

\* Salary estimates were obtained from the US Office of Personnel Management salary scale at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2022/general-schedule/>

## 15. Explanation for Program Changes or Adjustments

 This is a revised request to make minor edits to the original quantitative survey, to update the contact information in the consent form, and to add a new consent form and a new qualitative data collection tool. The changes to the approved consent and quantitative survey include:

* Updating the contact information in the consent forms for each project area
* Adding to the introduction section the final web address so the respondent can access the response cards
* Updating the branching logic for survey programming purposes
* Adding language to the Web-Based survey introduction to explain how participants can stop and resume the survey where they left off
* Removing the response option “Don’t know” from two questions
* Adding the response option “Don’t know” to one question
* Adding transition language before the local questions
* Adding code to import variables provided by staff in the project areas, such as diagnosis stage and date of diagnosis.

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

Data collection will be conducted during the 3-year period after OMB approval. Data analysis will occur within 12 months of final data collection. The following is a brief overview of the project timeline (Exhibit A.16.1).

**Exhibit A16.1: Project Time Schedule**

|  |  |
| --- | --- |
| **Activity** | **Time Schedule** |
| Data collection tools, sampling and data plans, study protocol development | 2-3 months before OMB approval |
| Recruitment   | Immediately after OMB approval |
| Data Collection   | 1 month – 3 years after OMB approval |
| Data management | 1 month – 3 years after OMB approval |
| Analysis  | Within 12 months of project completion |
| Publication | Within 12 months of project completion |

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

 The OMB Expiration Date will be displayed. No exception is requested.

## 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.