

**Identification of Behavioral and Clinical Predictors of Early HIV
Infection
(Project DETECT)**

Supporting Statement A

OMB No. 0920-New

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CONTACT:

Kevin Delaney
Epidemiologist, Special Studies and Diagnostics Team
Division of HIV/AIDS Prevention
Centers for Disease Control & Prevention
1600 Clifton Rd, NE, MS E-46
Phone (404) 639-8630
Fax (404) 639-8640
khd8@cdc.gov

Table of Contents

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

EXHIBITS

- Table A12A. Estimated Annualized Burden Hours
Table A12B. Estimated Annualized Burden Costs
Table A14. Annualized Cost to Government
Table A16. Project Time Schedule
Table B4. Table of Measures

Attachments

1. Public Health Service Act
2. 60-Day FRN
3. References
4. Certificate of Confidentiality Approval
5. IRB Approval
6. Phase 1 Enrollment Survey A
7. Phase 1 Enrollment Survey B
8. Phase 2 HIV Symptom and Care Survey
9. Phase 2 Behavioral Survey
10. Phase 1 Consent Form

- 11 Phase 2 Consent Form
- 12 Survey screen shots
- 13 Supplemental Study Information

Goal: The goals of the project are to: 1) characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care (POC), relative to each other and to currently used gold standard, non-POC tests, and 2) identify behavioral and clinical predictors of early HIV infection.

Intended Use: CDC provides guidelines for HIV testing and diagnosis for the United States, as well as technical guidance for its grantees. CDC will use the HIV testing data collected in this project to update these guidance documents to reflect the latest available testing technologies and their performance characteristics. CDC will use the information on behavioral and clinical characteristics of persons with early infection to help HIV test providers (including CDC grantees) more effectively target the tests designed to detect early HIV infection, which are the most expensive HIV tests, and are most appropriately used to test those at highest risk of infection.

Methods: Persons at high risk of HIV infection will be identified via a standard clinic intake form when they present to the main study site clinic for HIV testing, and persons with established and early HIV infection will be identified from participating clinics through routine HIV testing. In Phase 1, biological specimens from all persons who consent to participate will be tested with the seven HIV tests under investigation. Test performance and socio-demographic, behavioral and medical data collected via the Phase I enrollment questionnaire will be compared for persons at high risk, and persons with established and early infection. In Phase 2, participants with discordant test results in Phase 1 will undergo frequent follow-up testing to document seroconversion on all tests under investigation, until they become HIV positive on all tests, have consecutive negative test results on all tests (indicating reactive Part 1 tests were false-positive), or complete 70 days of follow-up.

Subpopulation: The primary study subpopulation will be persons at high risk for or diagnosed with HIV infection, most of whom will be men who have sex with men (MSM) because the majority of new HIV infections each year are among this population.

Analysis: Data will be analyzed using univariate and bivariate statistics and multivariate regression methods.

A. JUSTIFICATION

A. 1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a 3-year approval for a new data collection called "Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT)."

CDC awarded a contract to the University of Washington (UW) in 2014 to conduct Project DETECT. The project has two goals. The first goal is to characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care (POC), relative to each other and to currently used gold standard tests which are processed in a centralized laboratory rather than at POC. Currently available POC tests are less sensitive than those to be evaluated at detecting early HIV infection. The second goal is to identify behavioral and clinical predictors of early HIV infection. CDC staff will use data collected to update HIV testing guidelines. If differences in behavioral or clinical characteristics can be used to distinguish those most likely to have early infection, CDC will provide this information to HIV test providers to help them choose which HIV tests to use, and to target tests appropriately to persons at different levels of risk.

Background, Need and Circumstances Motivating the Request

An estimated 50,000 new HIV infections occur each year in the United States. Men who have sex with men (MSM) accounted for 67% of diagnosed HIV infections in 2012 (CDC 2014, reference in Appendix 3). Data from the National HIV Behavioral Surveillance System, collected in 2011 in 20 U.S. cities, indicated that 33% of MSM were unaware of their HIV infection (CDC 2013, reference in Appendix 3).

Early diagnosis of HIV infection has both clinical and public health benefits (Miller et al 2010, reference in Appendix 3). It allows diagnosed persons to receive treatment to stay healthy, and has also been shown to reduce risk behaviors, thereby decreasing the likelihood of transmitting HIV to others (Cohen et al. 2013, reference in Appendix 3).

Diagnosing persons during early infection is particularly important as it is during this phase that HIV-infected persons are highly infectious because of the large quantity of virus in their blood. In this early stage of infection, the body has not mounted an antibody response, so those who are recently infected may test negative for HIV antibodies. Many MSM and others at high risk are tested for HIV in settings where POC rapid tests are often used. These tests, which

typically are designed to detect HIV antibodies, cannot identify individuals with early infection and can provide false reassurance of HIV-negative status. If these MSM continue to engage in high-risk behaviors during this early phase of their infection, they may unwittingly be placing their sex partners at very high risk of acquiring HIV infection (Brenner et al., reference in Appendix 3).

Several new HIV tests have recently been approved by the US Food and Drug Administration (FDA), or are expected to be approved soon. These tests can be conducted using blood from a finger stick or oral fluid from a mouth swab. Some of the new tests can detect early infection by identifying the virus (called molecular tests), while other new tests can pick up early antibody response sooner than older HIV tests. Molecular tests are more expensive to conduct compared to currently available tests that only detect antibodies, so the feasibility of using these tests in POC settings may depend on the extent to which these tests can be targeted to those most likely to have early infection.

Although manufacturers seeking approval of HIV tests conduct studies to demonstrate device safety and efficacy, their clinical trials are not designed to evaluate important aspects that determine the public-health impact of these tests (e.g., the implementation logistics and feasibility of using different HIV tests for different populations in POC settings, such a doctor's office). In addition, these studies do not compare tests to one another and to currently use diagnostic tests analyzed in centralized laboratories rather than at POC. Therefore, CDC is sponsoring this data collection to assess the performance of these new HIV tests in point of care settings among persons at high risk of early HIV infection. This information is expected to be used to guide the efficient application of these new tests to maximize identification of HIV infections and further enhance the effectiveness of disease control efforts. Without this information CDC would not be able to exercise its leadership function with regard to identification and control of HIV infection.

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)**

A.2 Purpose and Use of the Information Collected

The Centers for Disease Control and Prevention (CDC) provides guidelines for HIV testing and diagnosis in the United States, as well as programmatic technical guidance for its grantees. CDC will evaluate HIV laboratory testing recommendations at least every five years and update guidelines when necessary. CDC will use data collected through this project, in conjunction with laboratory evaluations conducted at CDC, to inform HIV testing guidelines. In addition, data collected under this information collection request will provide information to help HIV test providers choose which HIV tests to use and to help them target tests appropriately to persons at different levels of risk.

The data collection will serve three primary purposes: 1) Compare the performance characteristics of new POC HIV tests for detection of early infection, 2) ascertain whether a questionnaire administered at clinic intake can identify persons at highest risk of infection (most likely to have early infection) accurately enough to target the use of POC tests for early infection, and 3) describe the potential impact of earlier diagnosis of infected persons for curtailing HIV transmission, as defined by incidence of specific sexual behaviors and activities.

For this project, it is expected that one of the largest samples to date of persons with early HIV infection will be assembled, providing a unique opportunity to better understand the behavioral and clinical predictors of early infection.

The study conducted by the University of Washington (UW) at the Public Health Seattle and King County (PHSKC) STD Clinic is a 6-year study conducted in three concurrent phases (see Figure 1.1) with information collection at phases 1 and 2. A pre-study screen based on risk behavior reported on the clinic's standard intake forms will comprise a phase 0 which is not part of this information collection request (see **Attachment 13**, Figure A). Approximately 12,500 persons per year presenting for an HIV test at the PHSKC STD Clinic will complete the standard intake form which will be used in this study to limit the evaluation of the new testing technologies in phase 1.

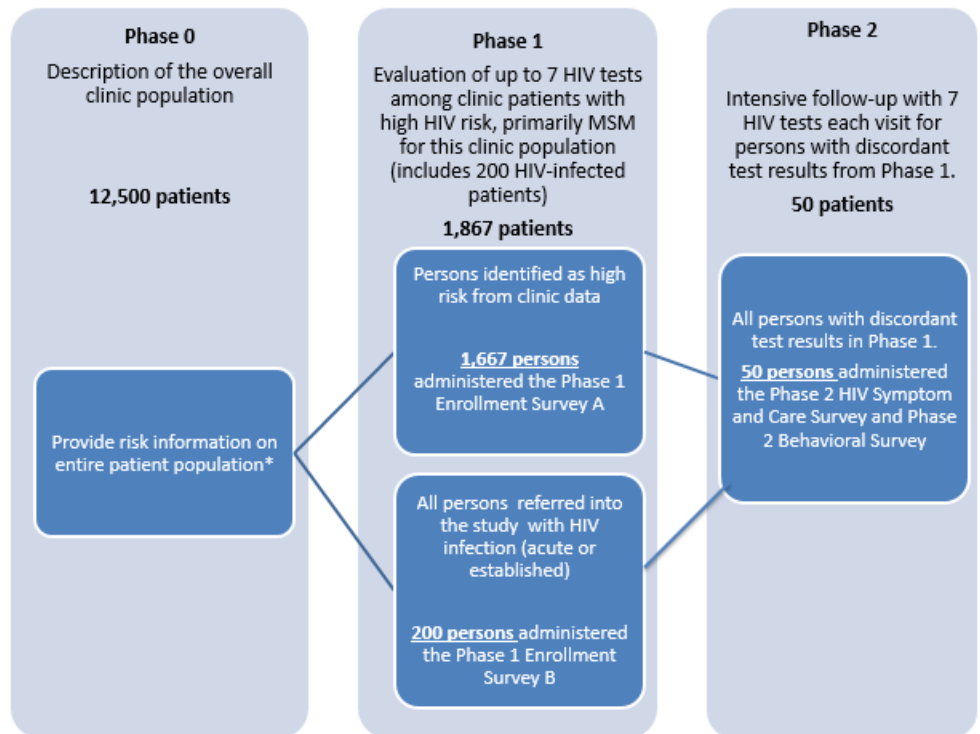
Phase 1 is limited to up to 200 HIV-infected persons per year (recruited from the PHSKC STD clinic or other clinic partners who offer HIV testing to increase the sample size for the evaluation of test performance [objective 1]) and up to 1,667 MSM at highest risk for HIV infection (recruited from the PHSKC STD clinic). In phase 1 of the study we will evaluate test performance (objective 1) by collecting specimens for testing with the HIV testing technologies being evaluated (see **Attachment 13**, Table 1). All test results, as well as results from an additional behavioral survey (Enrollment

Survey A or B: **Attachments 6 and 7**), will be reported to the CDC (for evaluation of objective 2; see **Attachment 13**, Figure A). Phase 1 participants with discordant test results (i.e., those with reactive results on at least one screening test and non-reactive results on another screening test), will be eligible for Phase 2.

In phase 2 we seek to describe the difference in days to detection for the new HIV tests on different specimen types collected (objective 1). Phase 2 participants will undergo frequent follow-up testing until they are positive on all tests being evaluated, or until they have two consecutive visits with negative test results on all tests (indicating reactive phase 1 tests were false-positive), or completion of 70 days of follow-up. At each return visit a Symptom and Care Survey (**Attachment 8**) will be administered to assess the presence of symptoms during HIV seroconversion (objective 2) and the effects of HIV treatment on test performance (objective 1).

It is expected that approximately 50 participants per year will enter phase 2 of the study, of which approximately 16 participants will complete the study with false positive results and approximately 32 participants will complete phase 2 follow-up with seroconversion. Based on previous experience in the clinic, we expect that approximately 2 participants who begin phase 2 of the study will be lost to follow-up. A follow-up behavioral survey (**Attachment 9**) will be conducted at the end of phase 2 to assess changes in behavior after diagnosis (objective 3). All test results, as well as results from the Symptom and Care Surveys (**Attachment 8**), and the follow-up Behavioral Survey (**Attachment 9**) will be reported to the CDC (see **Attachment 13**, Figure A).

Figure 1.1. Description of Study Phases



* Risk information is collected through an instrument used routinely in the clinic for all patients (regardless of participation in this study) and is part of the de-identified data sent to CDC under the requirements of the contract.

The information from this study will be used to help HIV providers more effectively target the tests designed to detect early HIV infection, which are the most expensive HIV tests, and are most appropriately used to test those at highest risk of infection. To identify predictors of seroconversion, such as differences in sexual and illicit drug use behaviors and clinical signs of early infection, behavioral and clinical characteristics will be compared among uninfected persons, persons with early infection and persons with established infection (objectives 2 and 3).

The University of Washington’s clinical site is well suited for this work, given the high testing rates and high incidence rates among MSM in Seattle. Because men living in Seattle are encouraged to test multiple times per year, the Clinic has a high probability of identifying early HIV infection among those who do test positive.

CDC provides guidelines for HIV testing and diagnosis for the United States, as well as technical guidance for its grantees. CDC will use the HIV testing data collected in this project to update these guidance documents to reflect the latest available testing technologies, their performance characteristics, and considerations regarding their use. CDC will also use information collected to describe behavioral and clinical characteristics of persons with early infection to help HIV test providers (including CDC grantees)

choose which HIV tests to use and guide them to target tests appropriately to persons at different levels of risk. This information will primarily be disseminated through guidance documents (e.g., guidelines for HIV testing in non-clinical settings) and peer-reviewed journal articles. While the population of Seattle/King County may not be as diverse as in some other areas, and the culture may not mirror that of other geographic regions, there is value in understanding the behavioral characteristics.

To prepare for the data collection covered under this information collection request, a pilot is being conducted with up to 9 Phase 2 study participants. The objective of the pilot is to determine how clinic flow would be impacted by the project and identify the exact sequence of project activities. The survey instruments will not be modified based on the results of this pilot. Preliminary results of the pilot have been used to streamline study procedures to improve efficiency and reduce the overall time the participant is in the clinic. Study staff have determined that administering the HIV tests first, then having the participant complete the visit survey while the tests are processing, has been both feasible for study staff and acceptable to study participants.

A.3 Use of Improved Information Technology and Burden Reduction

One hundred percent of the proposed information collection will be collected via an electronic Computer Assisted Self-Interview (CASI) survey. Participants will complete the surveys on an encrypted computer, with the exception of the Phase 2 Symptom and Care Survey, which will be administered by a research assistant and then electronically entered into the CASI system. Use of the CASI minimizes burden by efficiently moving the user through skip patterns automatically and at their own pace. For the Phase 2 survey administered at each follow-up visit, the CASI software will pre-populate some information from the participant's last clinic visit (e.g., race/ethnicity, age) to further reduce time burden for the participants.

CASI-based data collection methods have additional benefits compared to paper surveys. These include: 1) pre-programmed skip patterns to ensure that respondents are not asked irrelevant questions, and 2) automated validation checks incorporated into the behavioral survey to assist the respondent when incomplete or implausible responses are provided. The latter eliminates the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset.

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

We reviewed currently funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that collects data on the association of results from multiple HIV tests in point of care settings with behavioral and clinical predictors of early HIV infection.

A.5 Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

A.6 Consequences of Collecting the Information Less Frequently

The proposed project involves a one-time data collection from Phase 1 participants. Phase 2 participants will be followed up only until their test results are concordant. There are no legal obstacles to reducing burden.

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

This request fully complies with regulation 5 CFR 1320.5.

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

A 60-day federal register notice to solicit public comments was published on **May 13, 2015, Volume 80, Number 92, Pages 27311-27313 (Attachment 2)**. **No comments have been received.**

Consultations were conducted in March 2014 with HIV testing facilities serving MSM in different regions of the United States. All names, affiliations and contact information are included in Table 8-A-1. The consultations were conducted to assess the feasibility of the proposed evaluation of HIV tests and behavioral data collection for the project. In addition, experts provided feedback on the behavioral and clinical indicators that would be most relevant to collect for this project.

Table A-8-1: Persons Consulted in the Development of Project DETECT

Los Angeles Gay and Lesbian Center Risa Flynn, Research Program Manager rflynn@lagaycenter.org Bob Bolan, Medical Director and Director of Clinical Research 1625 N. Schrader Blvd Los Angeles, CA 90028-6213	Whitman Walker Clinic Dr. Rick Elion, Director of Clinical Research relion@whitman-walker.org Meghan Davies, Director of Community Health Mdavies@whitman-walker.org Justin Schmandt, Research Manager
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<p>323-993-7400 bbolan@lagaycenter.org</p>	<p>jschmandt@wwc.org Megan Coleman, Research Coordinator/Nurse Practitioner mcoleman@whitman-walker.org</p> <p>1701 14th St, NW Washington, DC 20009 202-745-7000</p>
<p>Callen-Lorde Clinic Anita Radix, Director of Clinical Research 356 W 18th St New York, NY 10011 212-271-7200 ARadix@callen-lorde.org</p>	<p>Howard Brown Clinic Daniel Pohl, Director of HIV/STI Prevention Danielp@howardbrown.org David Munar, President and CEO DMunar@howardbrown.org Kristin Keglovitz, Associate Medical Director KristinK@howardbrown.org 4025 N. Sheridan Road Chicago, IL 60613 773-388-1600</p>

A.9 Explanation of Any Payment or Gift to Respondents

Recruiting participants with early HIV infection and retaining them is central to the success of the proposed research project. To promote recruitment and retention, given the intensive follow-up process and discomfort of specimen collection, tokens of appreciation will be provided to respondents.

Incentives paid to respondents have been shown to increase response rates, which in turn improves the validity and reliability of the data (Abreu and Winters 1999; Shettle and Mooney 1999; full references in **Attachment 3**). A meta-analysis of survey methodologies (Church 1993; reference in **Attachment 3**) found that cross-sectional studies using prepaid monetary incentives yielded an average increase in response rates of 19.1 percentage points, representing a 65% average increase in response. Edwards et al. (2002, reference in **Attachment 3**) reported similar results in a subsequent meta-analysis. With very few exceptions, reports of more recent experiments are consistent with results reported by Church and Edwards et al. These results support the use of tokens of appreciation in phase 1 of the proposed study, which has a cross-section design. Jackle and Lynn (2008, reference in **Attachment 3**) found that incentives at multiple visits in a longitudinal study decreased attrition at all visits. In addition, other federal surveys use respondent incentives. For example, the National Health and Nutrition Examination Survey (NHANES, OMB No. 0920-0950, exp. 11/30/2015), which combines

questionnaire responses and physical examinations, as for Phase 2 of the proposed project, has used incentives since it began in the 1960s. Incentives for the 2013-2014 NHANES data collection cycle equaled or exceeded the amounts for the proposed study (NHANES Interviewer Procedures Manual, March 2013, reference in **Attachment 3**).

For the proposed data collection, the Contractor will provide \$40 to participants for the Phase 1 study visit and \$50 per study visit for participants followed longitudinally in Phase 2. The token amounts in this study are consistent with a recent HIV testing study conducted by UW among MSM in the Seattle metropolitan area (Stekler et al 2013, reference in **Attachment 3**). This study differs from the previous UW study in that the previous study consisted of a one-time clinic visit without collection of any type of blood or oral fluid specimen. The current study is substantially more intrusive as it involves:

1. study visits with specimen collection procedures that can be uncomfortable (e.g., oral swabs and a venous blood draw for Phase 1, and for Phase 2, oral swabs, 6 finger stick blood draws and a venous blood draw every few days for up to 70 days - which though not dangerous are painful and medically unnecessary);
2. requests for sensitive information about participants' behavior during each visit (Enrollment Survey in Phase 1; and for Phase 2, 5 minutes for the Symptom and Care Survey and 30 minutes for the Behavioral Survey).
3. repeated travel to the clinic every few days to undergo study procedures which is inconvenient as the clinic does not have extended hours.

Without providing the tokens of appreciation, UW would not be able to recruit and retain the required number of individuals necessary to meet the goals of the study in the required timeframe.

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

The CIO's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply to this activity because any personally identifiable information (PII) is collected as part of standard clinic intake forms that are not collected exclusively for this study and only de-identified data are sent to CDC. A Certificate of Confidentiality has been obtained by the UW (**Attachment 4**). The de-identified, but sensitive information from the behavioral surveys will be transmitted monthly to the CDC via an encrypted File Transfer Protocol (FTP) site. At no time will CDC receive any identifying information such as names; instead, CDC

will receive datasets containing a unique identification number (ID) for each participant. The database maintained by UW must be approved through the Data Security Certification and Accreditation process overseen by the CDC Information Technology Office.

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

IRB Approval

The protocol for Project DETECT has been reviewed and approved by UW's Institutional Review Board (IRB). The approval letter is included as **Attachment 5**. The IRB-approved questionnaires are included as **Attachments 6, 7, 8 and 9** and the approved consent forms are included as **Attachments 10 and 11**.

The objectives of Project DETECT and its goal to inform HIV testing guidelines and HIV test providers regarding diagnosing early HIV infection cannot be accomplished without the collection of sensitive information regarding HIV risk, such as sexual behavior, drug use behavior (including injection drug use), as well as information on HIV/AIDS status, medical history and sexual orientation. Collection of these data will be used to identify predictors of early HIV infection, which can help HIV test providers more effectively use the tests designed to detect early HIV infection, which are the most expensive HIV tests.

Sensitive Questions

The context in which questions will be asked helps to overcome their potential sensitivity and to emphasize to the respondent the legitimate need for the information:

- a. Nearly all questions allow for responses of "don't know" or "refuse to answer."
- b. Consent forms make it clear that the survey is sponsored by CDC and implemented by UW and that the information will be put to important uses (**Attachments 10 and 11**).
- c. Local phone numbers are provided if the participant has questions about the survey.
- d. The questionnaires (except for the HIV Symptom and Care Survey in Phase 2) are self-administered and carefully organized to lead smoothly from one topic to another. Transitions are made clear to participants and the need for the information explained.
- e. Assurances about the privacy of the data are reiterated.

A.12 Estimates of Annualized Burden Hours and Costs

The estimate of annualized burden hours for this data collection is 2,111 hours; details are provided in exhibit 12.A. For the proposed information collection, approximately 2,334 persons will be recruited annually into the study and undergo the consent process (2,084 from the PHSKC STD clinic and 250 referred from clinics in the Seattle area). The participant will take approximately 15 minutes to read the Phase 1 consent form.

We estimate that 20% of persons approached and consented will not be interested in completing the HIV testing and behavioral survey. Therefore, it is estimated that 1,867 will participate in Phase 1 of the study during each 12-month period. Of these 1,867 participants 1,667 will be recruited from the PHSKC STD Clinic and will complete the Phase 1-Enrollment Survey A, which is estimated to take 45 minutes, and 200 will be referred from other clinics and will complete the Phase 1 - Enrollment Survey B, which is estimated to take 60 minutes.

Among these 1,867 participants from Phase 1, an estimated maximum of 50 persons will participate annually in Phase 2 of the study. Reading the Phase 2 consent form is estimated to take 15 minutes. Completion of the Phase 2 HIV Symptom and Care Survey is estimated to take 5 minutes for each of up to 9 follow-up visits. The Phase 2 behavioral survey will be completed at the end of follow-up and is estimated to take 30 minutes.

Exhibit A12A. Estimate of Annualized Burden Hours					
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Minutes Per Response	Total Response Burden (Hours)
Persons eligible for study	Phase 1 Consent	2,334	1	15/60	584
Enrolled participants	Phase 1 Enrollment Survey A	1,667	1	45/60	1,250
	Phase 1 Enrollment Survey B	200	1	60/60	200
	Phase 2 Consent	50	1	15/60	13
	Phase 2 HIV Symptom and	50	9	5/60	38

Exhibit A12A. Estimate of Annualized Burden Hours					
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Minutes Per Response	Total Response Burden (Hours)
	Care survey				
	Phase 2 Behavioral Survey	50	1	30/60	25
Total					2,110

Exhibit A12B. Estimated Annualized Burden Costs				
Type of Respondent	Form Name	Total Burden Hours	Hourly wage rate	Total respondent costs
Persons eligible for study	Phase 1 Consent	584	\$22.13	\$12,924
Enrolled participants	Phase 1 Enrollment Survey A	1,250	\$22.13	\$27,663
Enrolled participants	Phase 1 Enrollment Survey B	200	\$22.13	\$4,426
Enrolled participants	Phase 2 Consent	13	\$22.13	\$288
Enrolled participants	Phase 2 HIV symptom and care survey	38	\$22.13	\$841
Enrolled participants	Phase 2 Behavioral Survey	25	\$22.13	\$553
Total				\$46,695

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

Record Keepers

The annualized cost to respondents for the burden hours is estimated to be \$46,694; details are provided in Exhibit A12.B. The estimates of hourly wages were obtained from the U.S. Department of labor (Bureau of Labor Statistics Wage Data

(<http://www.bls.gov/news.release/pdf/ecec.pdf>).
<http://www.bls.gov/oes/current/oes434111.htm>

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

A.14 Annualized Cost to the Government

The annualized cost to the government is \$867,704. The cost of this project for the three years is estimated to be \$2,603,112.

Expense Type (Based on FY14 dollars)	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	DETECT Personnel	
	Epidemiologist-13 (1) 100%	\$101,754
	Epidemiologist-14 (1) 100%	\$120,243
	Site Visit (1 trip x 2 staff)	\$3,000
	Total direct costs to federal government	\$224,997
Contractor and Other Expenses*		
	Salary and Wages	\$208,887
	Supplies and Materials	\$45,272
	Retirement and Benefits	\$60,846
	Facilities and Administration	\$226,708
	Other Contractual Services	\$100,994
	Total contractor and other expenses	\$642,707
	TOTAL COST TO THE GOVERNMENT	\$867,704

*Salary estimates were obtained from the US Office of Personnel Management salary scale at <http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/ATL.pdf>.

The personnel related to the Project DETECT data collection include project officers (epidemiologists) at the GS-13 and 14 levels.

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

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

Data collection will be conducted during the 3-year period after OMB approval. It is expected that the project will take 6 years to complete and the investigators anticipate submitting an extension request after 3 years. Data analysis will occur within 12 months of final data collection. The following is a brief overview of the DETECT Timeline.

Exhibit 16.A Project Time Schedule

Activity	Time Schedule
Initiate recruitment	Immediately after OMB approval
Conduct Phase 1	1 month - 3 years after OMB approval
Conduct Phase 2	2 months - 3 years after OMB approval
Data management	1 months - 3 years after OMB approval
Analysis	Within 6 months of project completion
Publication	Within 12 months of project completion

A.17 Reasons(s) Display of OMB Expiration Data is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.