HIV Incidence and Case Surveillance Branch project

Assessing the Accuracy of Self-Report of HIV Testing Behavior

Generic Information Collection Request under 0920-0840
Expiration 31 January 2013

Supporting Statement
Part A

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Request for Sub-collection Under the
Approved Generic ICR: Formative Research and Tool Development

Assessing the Accuracy of Self-Report of HIV Testing Behavior

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval for a formative study assessing the accuracy of self-report of HIV testing behavior that supports formative research in HIV/AIDS surveillance. The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) conducts HIV incidence surveillance using self-reported behavioral data in conjunction with results from a serologic testing algorithm to estimate HIV incidence in the United States. The accuracy of self-recall of HIV testing behavior is not known. This activity will provide information about how respondents answer questions and ways in which question response bias and error can be reduced. Overall, this self-report validation module is intended to provide information that will increase the success of the surveillance through increasing response rates and decreasing response error thereby decreasing future data collection burden to the public.

A.1.2 Privacy Impact Assessment

The grantee, Houston Department of Health and Human Services, will collect information in identifiable form. Information will be collected using computer-assisted self-interview (CASI) at the HIV testing or clinical follow-up visit location site. The local study staff will collect information in identifiable form, such as names, date of birth, and race/ethnicity as well as medical record numbers for the purpose of medical record abstraction for HIV test results, HIV testing dates and ARV usage. Information will be collected on subject’s recall of past HIV testing and use of antiretroviral (ARV) medications. CDC will not receive any personally identifiable information. All individually identifiable information collected by local partners will be unlinked or stripped from the database that is submitted to CDC. Surveys and medical record abstractions will be identified with unique pre-assigned codes. The only link to respondents’ names will be consent forms, to be housed in a locked file cabinet separate from all data forms.

A.1.3 Overview of the Data Collection System

Study subjects will be recruited at pre-selected clinical settings that perform HIV testing. Consent for both interview and medical records abstraction will be obtained at the time of recruitment. Self-reported data will be collected via computer-assisted self-interview (CASI) on HIV testing history, HIV status if known and history of ARV use. Medical records abstraction will be performed at the health care facilities identified by the patient as providing services in the previous 5 years for documentation of HIV testing history, HIV status and ARV use.

Recruitment, CASI administration and medical record abstraction will be conducted individually in a private setting by trained staff who currently work with the HIV surveillance program. Self-reported results obtained via CASI will be compared to medical record documentation of HIV testing at participating facilities. Results will contribute to formative research regarding the validity of self-report and analyzed for systematic bias. These results will inform our current incidence surveillance model which relies on self-report for critical information on testing frequency. Data collection tools may be used in a larger study on the validity of self-report of HIV testing behavior depending on the outcome of this pilot study. Information from this field testing may be used to improve methods, questionnaire instruments, and other materials in HIV surveillance and possibly in a larger study to reduce the burden of future data collections.

A.1.4 Items of Information to be Collected

*(***Attachment 1**) is the questionnaire instrument to be used in this pilot study via CASI. Data will be collected regarding:

- History of HIV testing including dates and testing locations
- HIV testing status
- History of ARV use
- Limited demographic information

Researchers conducting this study are currently engaged in HIV surveillance and covered by an existing Assurance of Confidentiality.

Personally identifiable information will be kept in a separate location and accessible only to the interviewer. This information will be destroyed when the client's contribution to the project has ended. The data bases created for CDC will not include personal information.

Medical records abstraction will be used to validate patient self-report against documentation in the medical record. Attachment 2 is the medical records abstraction form to be used. Data will be collected regarding:

- HIV test type and results

- Dates of HIV testing
- Facility or facilities at which HIV testing was performed
- History of ARV use
- Patient's most recent visit to this facility

A.1.5 Identification of Websites and Website Content Directed at Children Under 13 Years of Age

- This information collection does not involve websites or website content directed at children less than 13 years of age.

A.2. Purpose and Use of Information Collection

The specific purpose of this study is to validate the accuracy of the self-reported information collected via CASI against medical records documentation of HIV testing to improve HIV incidence surveillance.

The purpose of this information collection includes the following:

A.2.1 General methodological research

HIV incidence surveillance is performed in 25 state and city locations in the United States. The sample from which the national HIV incidence estimate is derived is comprised of new diagnoses reported to the HIV/AIDS surveillance system, information on HIV testing history (last negative test, first positive test, and number of times tested in the two years prior to testing positive), and antiretroviral medication use. If the self-reported information on HIV testing behavior is biased, the incidence of HIV infection in the United States will be over- or underestimated accordingly. The extent of bias in the recall of testing information must be assessed to determine the potential effect on the national HIV incidence estimate. The purpose of this study is to perform formative research on the accuracy of self-reported HIV testing behavior. This study will contribute to our knowledge of the accuracy of self-reported responses with regards to HIV testing, and may be used to improve the methodology used to estimate incidence.

A.2.2 Field testing of new methodologies and materials

HIV incidence estimation relies upon accurate self-reported information on HIV testing behavior and medication use. This information is routinely obtained through direct client interview

or medical chart abstraction. This pilot study will field test a new approach using CASI methodology.

A.2.3 Usability testing of technology-based instruments and materials

HIV testing and treatment history needed for HIV incidence estimation has not previously been obtained using CASI. Study researchers will be onsite to note reported difficulties the study population have with CASI technology.

This study does not propose to produce results that can be generalized beyond the scope of the study. The objective of this request is to enable NCHHSTP/DHAP to improve the quality of the data collection systems and respond to the needs of the affected persons and the community in a timely manner. The improved data quality will decrease burden to the public by providing better estimations of HIV incidence for program planning purposes.

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

Information will be collected using the most current modes of survey data collection, including computer-assisted self-interview (CASI). The nature of this study requires some direct interaction between respondents and project staff, but this will be minimized by use of CASI. "Skip patterns" incorporated in the CASI instrument will be used to reduce errors and public burden of data collection.

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

Studies examining HIV risk behavior self-report reliability at different recall periods have focused on short-term (1, 3 and 6 month recall) for sex and drug use behaviors. Although studies examining self-report reliability for date recall of last cholesterol screening, Pap smear, mammogram and other preventive health tests provide some information on accuracy of recall, it is not clear how these findings might relate to recall of dates of HIV testing. NCHHSTP identified studies examining accuracy of self-report of HIV status in a number of settings (e.g., correctional facilities), but these studies do not assess the accuracy of recall of dates of last negative and first positive tests, information that is critical in CDC's estimation of HIV incidence. NCHHSTP has verified that there are no other published studies that have looked specifically at the recall of HIV testing behavior including date of first positive HIV test and date of last negative HIV test among people for whom this

information can be verified.

A.5. Impact on Small Businesses and Other Small Entities

This collection request does not involve burden to small business or other small entities. This research activity involves data collection from medical offices, publically-funded clinics and hospitals. The research team will work with such entities to generate lists of potential study participants and to provide medical records to study staff to review.

A.6. Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

For sub-collection requests under a generic approval, Federal Register notices are not required and none were published. No other agency was consulted for the development of this request

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

Project participants will be offered a $10 gift card token of appreciation for the time needed to complete the CASI.

Eligibility criteria for respondents are specific to HIV testing status and enrollment is restricted to a limited number of health care facilities who have agreed to participate in this study. This eligibility requirement restricts the population from which we can sample and it may be more difficult to recruit eligible respondents; reimbursement for interview participation time may help to attract difficult-to-recruit subjects. The amount of the reimbursement is based on reimbursements offered in similar studies performed in this jurisdiction involving comparable time or burden. For example, participants in this jurisdiction involved in 30 minute interviews have been reimbursed $40. In this proposed study we estimate the average interview duration will be 15 minutes. The $10 reimbursement is considered appropriate and necessary on this basis.

A.10. Assurances of Confidentiality Provided to Respondents

Local project staff will have identifying information as part of the sampling procedure and follow up medical record review. This information will be removed from any data sent to CDC, and CDC will, at no time, have access to any local data that contains identifiers. Local project staff will verify that any individually identifiable information that has been collected during the course of their activities has been removed from information transmitted to or shared with CDC.

This proposed activity is part of the development of the HIV surveillance system and, as such, is covered under the HIV Surveillance Assurance of Confidentiality awarded under CDC's statutory authority according to section 308(d) of the Public Health Service Act (42 USC 242m). As CDC will not be directly involved in conducting this study, there is no need for CDC IRB approval. Local IRB approval is pending.

Informed consent
Participation in this study is strictly voluntary. Written informed consent will be obtained immediately prior to the start of information collection. Participants will be allowed to ask questions about the project before deciding whether to participate or not. The consent form describes the purpose of the study, specifies specific procedures that will be conducted, and describes security protections for the respondent's information. (**Attachments 3a and 3b** in English and in Spanish respectively).

A.11. Justification for Sensitive Questions

The purpose of this study is to assess the accuracy of self-reported HIV testing behavior. This study involves interviewing respondents about sensitive topics (e.g., HIV status) in order to investigate the presence of systematic bias in self-report of HIV testing behaviors in the overall study group or in sub-populations.

In no case will a participant's social security number be obtained.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A. Estimated Annualized Burden Hours

The response burden for 900 individual collections in this study is estimated at 375 hours in one year. Exhibit A.12.A provides details about how this estimate was calculated. Timings were conducted during instrument development process and pilot testing to support the overall burden per respondent. Obtaining informed consent is estimated to take 5 minutes. Completion of the CASI questionnaire is estimated to take 15 minutes. Obtaining medical records is estimated to take medical records staff time 5 minutes per record retrieved for review. The estimated average chart abstraction time of 15 minutes/chart was based on researcher experience in doing a chart abstraction limited to lab data regarding documented HIV tests.

The study design calls for a sample size of at least 900 subjects to allow for stratification at least by age and race/ethnicity for each of three categories of HIV tester: those who have tested HIV positive, those whose last HIV test was negative, and those who have never been tested.

Exhibit A.12.A Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
General public	Informed Consent	900	1	5/60	75
General public	Survey of individual (CASI)	900	1	15/60	225
Medical records retrieval and abstraction	Medical records abstraction	10	90	20/60	300
Total					**600**

A.12.B. Estimated Annualized Costs

The annualized costs to respondents are described in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of Labor (Bureau of Labor Statistics Wage Data http://www.bls.gov/bls/wages.htm) Based on the annual 2010 estimate for median usual weekly earnings (second quartile), employed full time, wage and salary workers noted here, we estimated an hourly wage rate of $18.65 for the general public. The mean hourly wage of medical records personnel in 2010 listed by the Bureau of Labor Statistics Wage Data is $16.29. The mean hourly wage for survey researchers of $20.35 was used for

calculating costs for staff performing medical records abstraction. For the calculation below, medical records retrieval and abstraction have been combined into one line with the higher hourly wage rate of $20.35 used in our calculations.

Exhibit A.12.B. Annualized Cost to Respondents

Type of respondent (form name)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
General public (Consent Form)	75	$18.65	$1,398.75
General public (CASI)	225	$18.65	$4,196.25
Medical records personnel (to retrieve charts) and medical record abstraction	300	$20.35	$6,105.00
Total	**600**		**$11,700.00**

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

None. There are no other costs to respondents or record keepers.

A.14. Annualized Costs to the Federal Government

This activity will involve participation of one CDC project officer who will assist with project design, obtaining IRB and OMB approvals, and providing project oversight. A contracting data manager will be involved to provide technical support during data collection and analysis.

The annualized costs to the government are described in Exhibit A.14.B. The estimates of hourly wages were obtained from the Department of Labor (Bureau of Labor Statistics Wage Data http://www.bls.gov/bls/wages.htm)The costs for informed consent and CASI administration, medical record abstraction, and data management and the study site is included in the cooperative agreement annual cost listed in the table below.

Exhibit A.14.B Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (Commissioned Corps, 0-6, 0.1 FTE)	$18,000
Data Analysis	CDC Data Manager (GS-9/10, 0.25 FTE)	$20,000
	Subtotal, direct costs to the government	**$38,000**
Cooperative Agreement	Cooperative Agreement with the Houston Department of Health and Human Services Cost of software application for CASI, informed consent and CASI administration, data management and analysis at the study site	**$183,522**
	TOTAL COST TO THE GOVERNMENT	**$221,522**

A.15.Explanation for Program Changes or Adjustments

Not applicable – request is for a sub-collection under a generic approval.

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

Data collection will be completed during the first year after OMB approval is granted. Data collection included participant enrollment, informed consent process, CASI survey completion and medical records abstraction. Data analysis will be ongoing during data collection to inform sampling strategy and will be completed at 12 months after OMB approval. Report of findings will begin 12 months after OMB approval. Further statistical analysis may be performed by CDC but is not part of this generic information collection request.

Exhibit 16A Timeline

Activity	***Time Schedule***
Participant enrollment, data	*1-12 months after OMB approval*

collection	
Data analysis	*Ongoing during data collection*
Report of findings	*12 months after OMB approval*

A.17.Reason(s) Display of OMB Expiration Date is Inappropriate
OMB Expiration Date will be displayed.

A.18.Exceptions to Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification.