I-Catalyst Program - NCHHSTP HIV Guidelines

GenIC Submission under OMB #0920-1158

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GenIC Package & Attachments

1. Supporting Statement A
2. Att. 1: I-Cat Interview Protocol Guide and Questions
3. CDC I-Catalyst Request Template

- The Division of HIV/AIDS Prevention (DHAP) team is trying to explore strategies to improve the cost effectiveness of the HIV guidelines development process as well as characteristics of an evidence-based guideline that are most important to care providers and how this may influence guideline impact (e.g. dissemination, acceptability, uptake, and adherence).

- The CDC project team will conduct 30-minute, semi-structured interviews with HIV care providers respondents (clinicians, nurses, care team). Teams will use convenience sampling methods to select subjects who are readily available and within close proximity.

- Populations and customers to be interviewed will be clinical and non-clinical providers of HIV prevention and care services (i.e. primary care physicians & nurses who see HIV patients).

- Resulting data will be used for internal CDC discussion and decision-making. Findings will help the DHAP team identify how existing guideline processes and resources can be improved for greater

A. Justification

1. Circumstances Making the Collection of Information Necessary

The CDC Division of HIV/AIDS Prevention (DHAP) within the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has been at the forefront in developing guidelines on HIV prevention and care with significant national and international impact on public health care practice. Initiating the development of a standard guideline involves identification and proposal of suitable guideline topic(s) that meet a defined DHAP priority and its review and approval process. The Guideline development process in the division is very resource-intensive and takes a long time (3-6 years), yet DHAP sees low uptake and adherence (implementation) among providers. As guideline developers, DHAP wants to better understand how providers of HIV care and services seek and use guideline information to inform solutions that would lead to better uptake of CDC HIV guidelines.

The I-Catalyst subproject – NCHHSTP HIV Guidelines seeks OMB approval for a GenIC clearance. The ultimate goal of the I-Catalyst Project NCHHSTP HIV Guidelines is to understand how providers of HIV care and services seek and use guideline information. This information will be used to make internal decisions as to whether to pursue further development of solutions or not. The effort is authorized under Section 301 of the Public Health Service Act 42 U.S.C.241.

2. Purpose and Use of Information Collection

The CDC I-Catalyst program guides participants through a "customer discovery" process aimed at helping teams with a new solution to identify their customers. This is done by taking a team's main assumptions about who their customer is, the exact problem they are solving for the customer, and how the customer wants to receive or use the solution from the team—and turning those assumptions into hypotheses which the teams will then test (mainly through interviews with potential customers). Only conversations with potential customers (stakeholders) can provide the facts from which hypotheses are proven or disproven about whether a solution (product, process, etc.) creates value for the intended beneficiaries. It is expected that participants will leave the program with the ability to evaluate and translate their insights into solutions that have high levels of efficacy and user acceptability. The information collection is necessary to guide CDC project teams to create usable solutions that are customer centric and meaningful to users, whether it is adhering to recommendations, policies, protocol or interventions.

The goal of this project, which is nested within the I-Catalyst training program, is to solicit qualitative information from providers of HIV care and services that will be utilized internally by DHAP to facilitate and advance DHAP's efforts toward increasing uptake of CDC HIV care and prevention guidelines.

The collected information will be used for internal decision-making purposes and to provide suggestions for improving the current process by which HIV guidelines are developed and disseminated. Information gathered will be used by DHAP to make more informed decisions about the solution and will help the team determine if their initial ideas about a solution will be beneficial to the end-user or not. The information collected is not designed to drive important budgetary and/or public policy decisions.

3. Use of Improved Information Technology and Burden Reduction

The interviews will be conducted in person, on-site or by virtual video conference (Att. 1 – Interview guide). Using formative interview protocols allows the interviewer to follow the respondent's lead during in-person conversations. This wouldn't be possible if a list of fixed questions were used. This also is not possible if automated, technological-based collection techniques, such as a web-based survey, are used. On-site, in-person interviews allow interviewers to establish rapport with respondents and produce visual cues for interpreting responses that may require further probing or clarification. However, there are instances where teams can use improved information technology such as Skype or video conferencing for interviews to reduce the burden and provide flexibility in responder's schedule.

4. Efforts to Identify Duplication and Use of Similar Information

This is a unique I-Catalyst project and a new proposed solution. There is no existing database that can provide the level of detail about gaps in usage and implementation of CDC guidelines from clinical and non-clinical providers of HIV prevention and care services.

5. Impact on Small Businesses or Other Small Entities

Since the affected public are HIV care and service clinicians and nurses, which include a wide range of practitioners, there may be small entities of private practitioners. The project will minimize the impact on small business concerns and entities by keeping all interviews to no more than 30 minutes and number of questions asked to providers to 5 or fewer.

6. Consequences of Collecting the Information Less Frequently

Data is collected once at this stage in the discovery process, respondents will participate in an interview once lasting no more than 30 minutes.

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

This request fully complies with the regulation 5 CFR 1320.5. There are no special circumstances.

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

Not Applicable

9. Explanation of Any Payment or Gift to Respondents

There is no exchange of payment or gifts to respondents for the voluntary interviews.

10. Assurance of Confidentiality Provided to Respondents

Activities for this request do not involve the collection of Individually Identifiable Information.

11. Justification for Sensitive Questions

There are no sensitive data items to be asked of individual respondents. CDC Human Research Protection Office determined that data/IC is not research involving human subjects and IRB is not required - OADS Project Determination approval.

12. Estimates of Annualized Burden Hours and Costs

The HIV Guideline team will interview 50 respondents for this ICR. The project will interview be clinical and non-clinical providers of HIV prevention and care services (primary care physicians who see HIV patients & nurses), for an average of 30 minutes and maximum of 1 responses per respondent. Each project team will interview approximately 50 respondents. Annualized burden will be 25 hours and an estimated annualized burden cost of $1400.00.

Estimated Annualized Burden Hours

Table A: Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
HIV care & service providers	Interview Guide	50	1	30/60	25
Total					25

Table B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)	Hourly Wage Rate*	Total Respondent Costs
HIV care & service providers	Interview Guide	50	1	30/60	25	$56.00	$ 1400.00
							$ 1400.00

*Average of hourly wage from http://www.bls.gov/home.htm

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

There are no projected cost burdens for reporting.

14. Annualized Cost to the Government

a. The project cost is associated with the CDC project team members responsible for conducting the interviews. These figures were estimated as the sum of the anticipated direct labor; fringe and burden on direct labor.

Project Staff Oversight	Annual Cost
CDC Cost: Health Scientist (3% of Time)	$3,480.00
CDC Cost: Public Health Advisor (3% of Time)	$2,700.00
Total	**$6,180.00**

15. Explanation for Program Changes or Adjustments

This information collection request is a new submission.

16. Plans for Tabulation and Publication and Project Time Schedule

The proposed interviews will be conducted within 2-3 months after approval of GenIC. Interim reports will be developed, which will incorporate data collected from these sources in 2017 and 2018.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.