

I-Catalyst Program - Project 11: CGH- DGHT

GenIC Submission under OMB #0920-1158

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GenIC Package & Attachments

1. NOA
2. Supporting Statement A
3. ICR PRA Part II Worksheet
4. Att. 1: I-Cat Interview Protocol Guide and Questions

- Written information products (articles, research protocols, etc.) experience extensive delays during the clearance process within CDC's Division of Global HIV and TB, frustrating authors. Delays are frequently due to the absence of items that ensure the scientific work is compliant with the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). Access to relevant training and materials on CDC's scientific policies and procedures will help CDC Science Officer or PEPFAR grantees and staff to improve the quality of information products being developed and avoid long delays during the clearance process at CDC Headquarters.
- Teams will use convenience sampling methods to select subjects who are readily available and within close proximity.
- Populations and customers to be interviewed will focus on CDC Science Officer or PEPFAR grantees and staff working with President's Emergency Plan for AIDS Relief (PEPFAR) funded programs overseas and

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Office of Technology and Innovation (OTI) in the Office of Associate Director for Science at the Centers for Diseases Control and Prevention, encourages, fosters, and develops innovative science, technologies, processes and policies that support the CDC/ATSDR. Federal scientific agencies, like the CDC, rely on research and scientific findings to help them develop solutions to public health problems which ultimately are disseminated to customers and stakeholders for adoption and use. However, anecdotal and empirical data show that many well-meaning, robust solutions are never used or adopted by the intended customer. This has resulted in a path littered with failed and unused government sponsored outputs. 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’s adhering to recommendations, policies, protocol or interventions.

This request seeks approval for a GenIC approval for subproject I-Catalyst – DGHT. The ultimate goal of the I-Catalyst Project DGHT is to determine the knowledge skills, and abilities staff need to prepare high quality information products that are compliant with CDC’s policies and procedures on the conduct of research and science. The results of the project will help CDC develop a plan for providing training and resources to staff as they are deployed or hired to PERFAR funded countries. The efforts of CDC activities is authorized under Section 301 of the Public Health Service Act 42 U.S.C.241.

2. Purpose and Use of Information Collection

Written information products (articles, research protocols, etc.) experience extensive delays during the clearance process within CDC’s Division of Global HIV and TB, frustrating authors. Delays are frequently due to the absence of items that ensure the scientific work is compliant with the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). Access to relevant training and materials on CDC’s scientific policies and procedures will help CDC Science Officers and staff improve the quality of information products being developed and avoid long delays during the clearance process at CDC Headquarters. The results of the project will help CDC develop a plan for providing training and resources to staff as they are deployed or hired to PERFAR funded countries. The project

hypothesizes that staff trained in the ethical conduct of science and research will produce high quality products that will be cleared without long delays.

The information collected will be used for internal CDC decision making purposes and to provide suggestions for development of training solutions and resources for CDC science officers and other staff in PER FAR countries.

3. Use of Improved Information Technology and Burden Reduction

The interviews will be conducted in person, on-site, or virtually using Skype for Business (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. Other than proprietary business databases, there is no existing database that can provide the level of detail about the customer experiences, wants, and needs necessary to support innovations on data surrounding science officers and staff deployed to PER FAR funded countries job preparation and needed resources to assist in submitting quality written products for clearance.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this project.

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

Project DGHT team will interview 50 respondents for this ICR. The project will interview CDC Science Officers and other staff working in PEP FAR-funded programs overseas and other staff within DGHT who develop protocols and

design data collection projects requiring IRB approval. Interviews are expected to last for an average of 30 minutes and have a maximum of 1 responses per respondent. Annualized burden will be 25 hours and annualized burden cost of \$1500.00.

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.)
Science Officers in PERFAR countries	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
Average: CDC Health Scientist - Science Officers	Interview Guide	50	1	30/60	25	Average 60.00	\$1500.00
							\$ 1500.00

*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 (5% of Time)	\$4,000.00
CDC Cost: PH Advisor (2% of Time)	\$3,600.00
Total	\$7,600.00

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. There is no planned publication from this information collection. 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.