I-Catalyst Program - Project 6: NCCDPHP Sudden Unexplained Infant Death Investigation Reporting Form (SUIDIRF)

GenIC Submission under OMB #0920-1158

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GenIC Package & Attachments

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- In 1996, CDC released the original Sudden Unexplained Infant Death Investigation Reporting Form (SUIDIRF). The form is used to collect information at the scene of an infant death. This information is used by 2 primary groups: 1) the death certifier to better determine cause and manner of death; and 2) child death investigators to discuss infant death prevention strategies. Although the form has gone through several updates, CDC does not know how death certifiers and child death review teams perceive the usability and quality of the form. CDC is preparing to update the form again. CDC would like to know if death scene investigators will use an updated SUIDIRIF form because it improves their workflow.

- 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 child death investigators such as medical

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 – Sudden Unexplained Infant Death and the Investigation Report Form (SUIDIRF). The ultimate goal of the I-Catalyst Project SUIDIRF is to determine which components of the 10-year old SUIDIRF form that collects information at the scene of an infant death needs to be updated and what method of delivery (app, web-based fillable, etc.) do the primary user groups prefer, to improve its usability. The results of the project will help CDC teams make the case for support to advance important improvements and solutions of the SUIDIRF form that death certifiers and child death review projects value, which is critical for ensuring that critical data on infant death is captured. 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

In 1996, CDC released the original Sudden Unexplained Infant Death Investigation Reporting Form (SUIDIRF). Ten years ago, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) brought together Subject matter Experts (SMEs) to update the SUIDIRF form that collects information at the scene of an infant death. The form, known as Sudden Unexplained Infant Death and the Investigation Report Form (SUIDIRF) is used by 2 primary groups: 1) the death certifier to better determine cause and manner of death; and 2) child death review Projects to discuss infant death prevention strategies.

The SUIDIRF is important for several reasons:

- Standardizes data collection that may improve classification of sleep-related infant deaths.
- Assists in determining accurate cause of death by strengthening information about the circumstances of the death available before autopsy.
- Guides investigators through the steps involved in an investigation.
- Allows investigators to document their findings easily and consistently.
- Produces information that researchers can use to recognize new threats and risk factors for sudden unexpected infant death (SUID) and sudden infant death syndrome (SIDS).

When CDC updated the form 10 years ago, NCEZID did not consider child death review Projects and also did not ask end-users what they wanted. The form was not pre-tested. NCEZID will like to update the form and improve its usability as currently the form is not used to return back critical data. Prior work to determine need was found that the first needed step was to edit and update the form.

Therefore the project hopes to seek child review projects and end-users input in updating the form for usability through I-Catalyst and determine how best to support the needed updates, to improve usability for infant death reporting. The information collected will be used for internal CDC decision making purposes and to provide suggestions for improving development of public health solutions surrounding infant death. The customer interviews with medical examiners/forensic pathologists, law enforcement, death investigators, and child death review Projects will help gain important input in the areas of the form that is in need of updates.

3. Use of Improved Information Technology and Burden Reduction

The interviews will be conducted in person, on-site (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 infant data from the SUIDIRF form.

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 (Att. 5).

12. Estimates of Annualized Burden Hours and Costs

Project SUIDIRF project team will interview 50 respondents for this ICR. The project will interview medical examiners/forensic pathologists, law enforcement, death investigators, and child death review Projects for an average of 30 minutes and maximum of 1 responses per respondent. Annualized burden will be 25 hours and annualized burden cost of $727.42.

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.)
medical examiners/forensic pathologists; law enforcement; death investigators; child death review Projects	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: Medical examiners/forensic pathologists; law enforcement; death investigators; child death review Projects	**Interview Guide**	**50**	**1**	**30/60**	**25**	**Average 29.10**	**$727.42**
							$ 727.42

*Average of hourly wage of Healthcare emergency management staff) 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: Commission Corp (2% of time)	$ 3,000.00
CDC Cost: Health Scientist (5% of Time)	$4,000.00
CDC Cost: PH Advisor (2% of Time)	$3,600.00
Total	**$10,600.00**

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.