|  |
| --- |
|  |
| **I-Catalyst Program - NCIRD Influenza Surveillance** |
| GenIC Submission under OMB #0920-1158 |

|  |
| --- |
| Juliana K. Cyril, MPH, PhDDirector, Office of Technology and Innovation Office of the Associate Director for ScienceCenters for Disease Control and PreventionPh: 404-639-4639Fax: 404-639-4903Team Lead: Melissa Rolfes, NCIRD/OID/EPBSubmission Date:10-23-2017 |

Contents

[A. Justification 3](#_Toc496520047)

[1. Circumstances Making the Collection of Information Necessary 3](#_Toc496520048)

[2. Purpose and Use of Information Collection 3](#_Toc496520049)

[3. Use of Improved Information Technology and Burden Reduction 4](#_Toc496520050)

[4. Efforts to Identify Duplication and Use of Similar Information 4](#_Toc496520051)

[5. Impact on Small Businesses or Other Small Entities 4](#_Toc496520052)

[6. Consequences of Collecting the Information Less Frequently 4](#_Toc496520053)

[7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5 4](#_Toc496520054)

[8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency 4](#_Toc496520055)

[9. Explanation of Any Payment or Gift to Respondents 5](#_Toc496520056)

[10. Assurance of Confidentiality Provided to Respondents 5](#_Toc496520057)

[11. Justification for Sensitive Questions 5](#_Toc496520058)

[12. Estimates of Annualized Burden Hours and Costs 5](#_Toc496520059)

[13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers 5](#_Toc496520060)

[14. Annualized Cost to the Government 6](#_Toc496520061)

[15. Explanation for Program Changes or Adjustments 6](#_Toc496520062)

[16. Plans for Tabulation and Publication and Project Time Schedule 6](#_Toc496520063)

[17. Reason(s) Display of OMB Expiration Date is Inappropriate 6](#_Toc496520064)

[18. Exceptions to Certification for Paperwork Reduction Act Submissions 6](#_Toc496520065)

**GenIC Package & Attachments**

1. Supporting Statement A
2. Att. 1: I-Cat Interview Protocol Guide and Questions
3. CDC I-Catalyst Request Template
* The Epidemiology and Prevention Branch (EPB) project team in the National Center for Immunization and Respiratory Diseases (NCIRD) wants to explore whether local and state health departments may be interested in adapting methods used on the national level for Influenza surveillance and communication to the methods they currently use to produce their state- and local-level estimates.
* The CDC EPB project team will conduct 30-minute, semi-structured interviews with flu coordinators. 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 staff in state and local health departments (epidemiologists and surveillance officers) who analyze or synthesize influenza surveillance data and get questions every year about the burden and severity of the influenza season in their jurisdiction.
* Resulting data will be used for internal CDC discussion and decision-making. If local and state health departments indicate that adapting methods of flu surveillance used on the national level is feasible and acceptable, CDC will explore additional strategies for the implementation and diffusion of these methods.
* Simple analysis techniques will be performed to group, organize, and identify themes or repeated insights/feedback in the information collected. No statistical analyses is planned. The information gained through the interviews will be used to make internal decisions about acceptability, usage, and usefulness of methods and whether to pursue further development of solutions that promote a more consistent approach to the development and communication of local, state, and national estimates of influenza burden and severity. Generalization of results is not intended.

# A. Justification

### 1. Circumstances Making the Collection of Information Necessary

Influenza has a substantial impact in the United States each year. Flu-related hospitalizations in the U.S. ranged from a low of 140,000 (during 2011-2012) to a high of 710,000 (during 2014-2015). During the 2015-2016 flu season, CDC estimated that 310,000 people were hospitalized for flu-related illness, resulting in hundreds of thousands of hospitalizations and thousands of deaths. The severity of influenza disease in the United States can vary widely and is determined by a number of things including the characteristics of circulating viruses, the timing of the season, how well the vaccine is working to protect against illness, and how many people got vaccinated. CDC tracks severity principally through its national Influenza Surveillance System that monitors key indicators like the percentage of deaths resulting from pneumonia or influenza, rates of influenza-associated hospitalizations, pediatric deaths and the percentage of visits to outpatient clinics for influenza-like illness.

Influenza-related activities take up a substantial amount of effort by state and local health departments every year. These include monitoring the flu season, investigating and controlling outbreaks, and communicating with local government, the public, and the media. Influenza severity and impact varies geographically every season. In order to be prepared and respond most effectively during the influenza season, local, state, and national public health leaders ask questions such as: “How much disease is there in the population?” or “How bad is flu going to be this year?” Knowing the answers to these questions is vital to appropriately scaling the response to seasonal epidemics or pandemics. Currently, local and state health departments are employing various reporting methods for flu surveillance and these data are not complete or consistent with the methods used to produce national estimates.

In this GenIC, the Epidemiology and Prevention Branch (EPB) project team requests OMB approval to conduct semi-structured interviews with local and state department staff (epidemiologists and surveillance officers) who analyze or synthesize influenza surveillance data and receive questions every year about the burden and severity of the influenza season in their respective jurisdictions. The efforts of CDC activities are 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’s adhering to recommendations, policies, protocol or interventions.

The Epidemiology and Prevention Branch in the Influenza Division at CDC collects, compiles and analyzes information on influenza activity year-round in the United States and produces FluView, a weekly influenza surveillance report, and FluView Interactive, which allows for more in-depth exploration of influenza surveillance data. The U.S. influenza surveillance system is a collaborative effort between CDC and its many partners in state, local, and territorial health departments, public health and clinical laboratories, vital statistics offices, and healthcare providers, clinics, and emergency departments. Currently, these various partners on the local and state level are employing various reporting methods on flu surveillance and these data are not consistent or complete with national standards.

The CDC Epidemiology and Prevention Branch (EPB) team have developed new methods and tools to forecast and estimate influenza disease burden and severity at the national level. Given the geographic and temporal variability of flu outbreaks, national-level methods or information may be uninformative for state and local public health authorities. The project hopes to explore how CDC can support the development of data analysis tools that states can use to input local surveillance data and retrieve state/local-level disease burden or severity estimates (whether such tools are simple web-based tools or stand-alone tools), that will be used to make local influenza burden and severity estimates, consistent with the approach used and communicated on a national level by CDC.

The ultimate goal of this I-Catalyst project is to determine whether local and state health departments are interested in utilizing national tools to assist in making local influenza burden and severity estimates that are consistent with the approach used and communicated on a national level by CDC. The results of the project will help CDC teams make the case for support to advance important improvements and surveillance tools that customers value, which is critical for ensuring that the CDC continues to deliver on its public health mission.

The project team hopes to interview epidemiologists and surveillance officers in state and local health departments who analyze or synthesize influenza surveillance data and receive questions every year about the burden and severity of the influenza season in their respective jurisdictions. The customer interviews will help the project team determine if the proposed solution of standardized tools might be useful for local and state health departments (or not) in order to help drive decision about how to proceed on influenza surveillance data on a national, state and local level. 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. Other than CDC National Influenza Surveillance System, there is no existing database that can provide the level of detail about the customer experiences, issues, and needs necessary to support innovations on influenza related activities on the state and local level.

### 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 team will interview 50 respondents for this ICR. The project will interview state and local epidemiologists and surveillance officers, 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 $851.25.

**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.)** |
|  |
| epidemiologists and surveillance officers at state & local health departments | 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** |
|  |  |  |
| epidemiologists and surveillance officers on state & local level | Interview Guide | 50 | 1 | 30/60 | 25 | $34.05 | $ 851.25 |
|  |  |  |  |  |  |  | **$ 851.25** |

\*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

1. 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: Deputy Director (2% of time) |  $ 3,000.00 |
| CDC Cost: Health Scientist (3% of Time) |  $3,480.00 |
| CDC Cost: Executive Assistant (5% of Time) |  $3,600.00 |
| **Total** | **$10,080.00** |

### 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.