

# **Services and Value of State and Local Immunization Information Systems**

OSTLTS Generic Information Collection Request  
OMB No. 0920-0879

## **Supporting Statement – Section A**

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**Program Official/Project Officer**

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## Section A – Justification

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

#### Background

This data collection is intended to be conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. Data will be collected from 64 Immunization Information System (IIS) program managers across 50 state, 6 local, and 8 territorial public health departments acting in their official capacity for the first data collection (**Attachment A**). The second data collection under this request will include the 64 program managers mentioned and 64 immunization program managers, one of each per public health department.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under two of the ten essential public health services: #9) Evaluating effectiveness, accessibility, and quality of personal and population-based health services. #10) Research for new insights and innovative solutions to health problems.

Immunization information systems (IIS) , formerly known as immunization registries are population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. IIS maintain vaccination histories, track the immunization status of patients at the provider level, and perform other functional standards recommended by the Centers for Disease Control and Prevention (**Attachment B**). IIS are helpful in identifying and improving immunization rates in vulnerable populations and can also be valuable public health tools for infection control and outbreak prevention. In recognition of IIS as valuable tools for informing decisions regarding vaccination coverage across the United States, a Healthy People 2020 objective was established that 95% of children under 6 years of age have immunization records housed in a fully operational IIS (**Attachment C**).

Since 1993, the United States Public Health Service has invested millions of dollars for the development of IIS projects across the U.S. through the CDC 317 grant program (**Attachment C**). However, a comprehensive study of IIS operating costs and the effectiveness of CDC's investment has not been conducted in over 5 years. Up-to-date data on IIS financials and operations will fill in the information gap left since the previous examination described by Diana Bartlett et al. in 2006 and enable CDC to help state/local/territorial health departments improve immunization coverage and manage publicly-purchased vaccines (**Attachment D**).

Recently, the CDC, National Center Immunization Respiratory Diseases (NCIRD) sponsored a Blue Ribbon Panel (BRP) of experts from the IIS community who identified major challenges for providers, public health experts, and Vaccines for Children (VFC) awardees related to IIS (**Attachment E**). The panel identified two high priority items for investigation. Specifically, how can awardees:

- Sustain funding and resources to maintain, operate, and improve IIS to meet standards and scale for the future
- Promote, encourage and ultimately establish IIS interstate interoperability

The question of how to sustain funding and resources was addressed by panelists in two ways:

1. Funding: Identify who values IIS and why (i.e., identify IIS customers and beneficiaries and the services they receive and value).
2. Resources: Identify candidate services and functions for modularizing and sharing.

In support of the BRP recommendation, CDC would like to conduct data collection to assess the array of IIS services that are highly valued by IIS stakeholders. To this end, the purpose of this data collection is to create a unified view of existing and potential value in IIS operations to identify shared service opportunities, develop a core funding model, and identify alternative funding sources. The data collected will enable CDC to help IIS and state/local/territorial health departments improve immunization coverage and vaccine management, as well as provide guidance on long term program sustainability in an ever changing health care environment.

## **Privacy Impact Assessment**

### Overview of the Data Collection System

The data collection system consists of two data collection instruments, an Online Data Collection Instrument and an Interview Guide (**see Attachment F -Online Instrument-Web, Attachment G -Online Instrument -Word version and Attachment H - Interview Guide**). The online and IIS interview data collection instruments are designed to collect information on IIS services and value across similar categories with 27 questions in the Online Data Collection Instrument and 15 questions in the IIS Interview Data Collection Instrument. The online instrument will include the IIS program managers and was piloted with a group of 9 states' IIS program managers as respondents. In addition, the interview data collection instrument will include the IIS program managers and the immunization program managers who have specific knowledge on programmatic and business operations of the Immunization Program. The interview data collection instrument was also piloted with a group of 9 states' IIS program managers as respondents. Three respondents from each of the two groups received both the online and interview data collection instruments. Feedback from these two groups was used to refine questions as needed, ensure accurate programming and skip patterns, and establish the estimated time required to complete each data collection instrument.

CDC will supplement the online assessment with a more in depth interview data collection to gather detailed information on each of the 64 grantees. The interview data collection will be conducted after the online data collection and is designed to provide additional detail that investigators are unable to garner from online data collection alone. The online data collection will provide structured data that will enable analysis and comparison based on a common set of data elements. The interviews will then provide a basis for a more contextual understanding of the unique nature and issues of each IIS, and will provide clarification and validation of any ambiguous responses or skip questions thoroughly answered in the assessment, thereby reducing the burden on respondents.

### Items of Information to be Collected

The online data collection instrument consists of 27 questions of various types, including dichotomous, multiple response, and open-ended. A significant effort was made to limit questions requiring narrative responses and to include narrative optional questions for respondents to elaborate on their feedback if they choose to do so. The assessment will collect information on the following:

- a. **Process and Functionality** (questions 1-10); Information from respondents rating the degree to which IIS needs are met by the IIS services and the feasibility of sharing different IIS services with other IIS programs.
- b. **Financials** (questions 11-23); Explanation of development, maintenance, and operational costs, current and planned funding sources.
- c. **Assessment Feedback** (questions 24-27); Solicitation of respondent feedback on assessment questions and methodology.

The interview data collection instrument consists of 15 questions of various types, including multiple response and open-ended. Based on completeness of the information collected from the respondent in the online data collection instrument, the investigator will tailor or skip the open-ended questions in the interview data collection instrument. The assessment will collect information on the following:

- a. **Process and Organization** (questions 1-6); Description of any new process/quality initiatives based on unique functions identified in online data collection. Respondent's explanation of the relationship with the jurisdiction's immunization program and public health program.
- b. **Stakeholder Relationships** (questions 7-9); Explanation of respondent's perception of IIS value to stakeholders. Elaboration on the successes/challenges identified in the online data collection.
- c. **Financials** (questions 10-12); Clarification on financial information listed in online data collection, and lessons learned from attempts to secure alternative funding.
- d. **IIS Environment** (questions 13-15); Description of the effect of possible changes to the jurisdiction's legal framework on IIS operation. Explanation of the advantages/constraints of IIS technological setup.

### Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The data collection system involves using a web-based data collection instrument. Respondents will be sent a link directing them to the online assessment only (i.e., not a website). No website content will be directed at children.

## **2. Purpose and Use of the Information Collection**

The purpose of this information collection is to develop a better understanding of information specific to services and value of immunization information systems. In addition, the data collection will create a unified view of existing and potential value in IIS operations to identify shared service opportunities, develop a core funding model, and identify alternative funding sources.

Information derived from this assessment will help inform both CDC and the state/local/territorial public health officials responsible for IIS day-to-day operations. More importantly, it will be used to inform sustainability recommendations for CDC strategic planning for IIS. Results of the assessment will be used to strengthen relationships between the public health departments and its immunizing partners, enhance the impact and effectiveness of the IIS, and strengthen the support for IIS across the healthcare community. CDC is conducting a thorough assessment of IIS services and value across the following categories to:

- **Process and Functionality:** Identify candidate services and functions for modularizing and sharing.
- **Stakeholder Relationship with an IIS:** Identify who values IIS and why (i.e., identify IIS customers and beneficiaries and the services they receive and value).
- **Financials:** Understand the IIS grantee current financial situation, including major costs, funding sources, cost saving initiatives, and attempts to secure additional funding.

Furthermore, the results from this assessment will be used to understand the value of the CDC-funded grant program and gather information to inform improvements to future CDC investment. The proposed data collection activities will result in stronger state, local, and territorial immunization information systems and a stronger CDC that is better equipped to meet the needs of its grantee awardees and, subsequently, demonstrate the impact of its activities on public health. In addition, these findings will be used as input for future IIS management and CDC strategic planning for IIS by identifying current costs associated with IIS, developing an IIS Shared Services Catalog/implementation plan, and developing core funding and sustainment recommendations. Without collecting this information, it would be difficult to judge the value of the IIS and determine where to target future investment.

#### **Privacy Impact Assessment**

No individually identifiable information is being collected. Respondents will be sent a link to access the web-based data collection instrument (Survey Monkey<sup>®</sup>), including instructions and an estimated amount of time for completion. Survey Monkey<sup>®</sup> servers are kept in a locked cage, with digital surveillance equipment monitoring at the data center. Secure Sockets Layer (SSL) technology protects user information using both server authentication and data encryption, ensuring that data are safe, secure, and available only to authorized persons in a password-protected system.

### **3. Use of Improved Information Technology and Burden Reduction**

Data will be collected via two instruments:

1) A web-based questionnaire, administered using Survey Monkey<sup>®</sup>, will allow respondents to complete and submit their responses electronically. Web-based data collection reduces respondent burden by enabling easy access and completion at a convenient time and location. The online data collection will consist of either easy-to-read response selections or embedded text boxes. The online data collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 27 questions).

2) The diverse nature of each IIS organization and operation requires detailed data to supplement baseline information gathered in the online data collection. CDC has made an effort to minimize the burden on respondents by giving state public health officials sufficient advanced notice to schedule the interview and opting for a telephone interview if an in-person visit is not feasible (i.e. respondents do not have the time to accommodate additional logistics planning for an on-site visit). Additionally, several weeks prior to the interview, respondents will be sent the list of the interview questions for their convenience, but are not required to perform any additional preparation prior to the interview. CDC will review online data collection responses prior to the interview to identify sections/questions of the interview that may be skipped or topics requiring further clarification.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

Currently, there is no information available via web or existing literature that can substitute for the desired responses. CDC has conducted an extensive literature review of approximately 300 publications, conference presentations, and white papers. Existing data include information on IIS compliance with functional standards, but provide limited information on the value of those functions. The most recent comprehensive view of IIS costs is approximately 8 years old and fails to address IIS value or alternative financing. Additionally, the detailed data required to assure accountability of CDC investments in IIS through cooperative agreement mechanisms is not routinely collected.

Data collected via the two instruments will create a unified, national view of IIS operations. The data will also identify shared service opportunities, develop a core funding model, and identify alternative funding sources. The new information collected will fill a gap by permitting CDC to assess its investment in relation to the value of IIS services intended to assist state/local/territorial health departments in their immunization management activities, thus they are unique and not duplicative of other efforts.

#### **5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this data collection.

#### **6. Consequences of Collecting the Information Less Frequently**

This request is for a one-time data collection. There are no legal obstacles to reduce the burden.

Specifically, without this data there would be:

- No current information regarding the value of IIS services to various stakeholders, including local public health programs, providers, payers, hospitals, commercial health insurance, and schools to inform CDC strategic planning
- Less data-driven decisions that need to be made by CDC about funding allocation to state/local/territorial public health agencies in support of IIS services
- Persistent gaps in other existing information collections, because of limited timing, content, i.e. CDC would not have a clear and current understanding of the value of its investment in IIS and level of effort required by state/local/territorial health departments to track immunizations and vaccine inventory among their population
- Limitations to effective and timely assessment of governmental agencies ability to fulfill their public health mission by identifying populations at high risk for vaccine-preventable diseases and targeting interventions and resources efficiently across the United States

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

#### **9. Explanation of Any Payment or Gift to Respondents**

CDC will not provide payments or gifts to respondents.

#### **10. Assurance of Confidentiality Provided to Respondents**

There is no assurance of confidentiality provided to the respondents. Employees of state and local public health agencies will be speaking from their official roles and will not be asked, nor will they provide, individually identifiable information.

### **11. Justification for Sensitive Questions**

No information will be collected that are of personal or sensitive nature.

### **12. Estimates of Annualized Burden Hours and Costs**

The estimate for burden hours is based on a pilot test of the online data collection instrument by nine public health professionals. In the pilot test, the average time to complete the online data collection instrument including time for reviewing instructions, gathering needed information and completing the online data collection instrument, was approximately 30 minutes and 15 minutes of preparation time. Based on these results, the estimated time range for respondents to complete the online data collections is between 20 and 90 minutes, with 90 minutes as an outlier. For the purposes of estimating burden hours, we have calculated 45 minutes (i.e., 30 minutes of survey execution time plus 15 minutes of preparation time).

The estimate for burden hours is based on a pilot test of the interview data collection instruments by nine public health professionals. Based on the experience during the pilot, we are using an average of two resources per interview data collection for our estimate. We estimate the time per interview data collection to be two hours: one and a half hours to conduct the data collection and thirty minutes for the respondent to spend on logistics, scheduling, and preparation.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – general and operations managers in state government (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$37.06 is estimated for all 64 respondents completing the online data collection instrument and an average hourly wage of \$37.06 is estimated for all 128 respondents completing the interview. Table A-12 shows the estimated burden and cost information.

**Table A-12:** Estimated Annualized Burden Hours and Costs to Respondents



Data Collection Instrument	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Online Data Collection Instrument	IIS Program Manager	64	1	45/60	48	\$37.06	\$1778.88
Interview Data Collection Instrument	IIS Program Manager and Immunization Program manager	128	1	2	256	\$37.06	\$9,487.36
	<b>TOTALS</b>	<b>192</b>	<b>1</b>		<b>304</b>		<b>\$11,266.24</b>

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

There will be no direct costs to the respondents other than their time to participate in each data collection instrument.

### 14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be CDC staff (Contractors and FTEs) supporting the data collection activities and associated tasks.

The estimated total cost to the federal government is **\$205,910.10**. Table A-14 describes how this cost estimate was calculated.

**Table A-14:** Estimated Annualized Cost to the Federal Government

Staff (FTE or Contractor)	Average Hours per Collection	Average Hourly Rate	Average Cost
<b>CDC Project Manager (Operations Research Analyst) GS-13</b> Consultation with OMB package preparation, instrument development, data analysis, quality control and report preparation consultation.	30 hours	\$54.87	\$1,646.10
<b>Contractor</b> Instrument development, pilot testing, OMB package preparation, web-based data collection programming, data collection, data coding and entry, quality control, data analysis, and report preparation.	1200 hours	\$170.22	\$204,264
<b>Estimated Cost of Information Collection</b>			<b>\$205,910.10</b>

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

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

Results of this assessment will be used internally to provide CDC recommendations for IIS funding allocation and potential shared services to optimize IIS system efficiency. It is not anticipated that the assessment results will be published.

Project Time Schedule

- ✓ Design data collection tool.....(COMPLETE)
- ✓ Develop data collection protocol, instructions, and analysis plan.....(COMPLETE)
- ✓ Pilot test data collection tool.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- OMB approval..... (TBD)
- Conduct data collection..... (Open 5 weeks)
- Collect, enter, and analyze data.....(5 weeks)
- Prepare report (Interview Summary only).....(3 weeks)
- Disseminate results.....(5 weeks)

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

We are requesting no exemption.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

## **LIST OF ATTACHMENTS – Section A**

Note: Attachments are included as separate files as instructed.

- A. CDC Grantee List**
- B. IIS Functional Standards**
- C. Healthy People 2020 Brochure**
- D. Bartlett Study**
- E. BRP Summary**
- F. Online Instrument- Web**
- G. Online Instrument-Word**
- H. Interview Guide**