

**SUPPORTING STATEMENT Part A**

**For**

**A Novel Framework for Structuring Industry-Tuned Public-Private Partnerships and Economic  
Incentives for U.S. Health Emergency Preparedness and Response**

**Version 1.0**

**Date: 08/16/2017**

**Project Officer:**

**Eric G. Carbone, M.B.A., Ph.D.**

Director, Office of Applied Research (OAR)

Office of Science and Public Health Practice (OSPHP)

Office of Public Health Preparedness and Response (OPHPR)

Centers for Disease Control and Prevention

US Department of Health and Human Services

Phone: 404-956-9477

E-mail: [vlno@cdc.gov](mailto:vlno@cdc.gov)

# Table of Contents

- 1. Circumstances Making the Collection of Information Necessary..... 3
- 2. Purpose and Use of the Information Collection..... 4
- 3. Use of Improved Information Technology and Burden Reduction..... 5
- 4. Efforts to Identify Duplication and Use of Similar Information..... 5
- 5. Impact on Small Businesses or Other Small Entities..... 5
- 6. Consequences of Collecting the Information Less Frequently..... 5
- 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5..... 6
- 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.... 6
- 9. Explanation of Any Payment or Gift to Respondents..... 6
- 10. Assurance of Confidentiality Provided to Respondents..... 6
- 11. Justification for Sensitive Questions..... 8
- 12. Estimates of Annualized Burden Hours and Costs..... 8
- 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers..... 10
- 14. Annualized Cost to the Federal Government..... 10
- 15. Explanation for Program Changes or Adjustments..... 10
- 16. Plans for Tabulation and Publication and Project Time Schedule..... 10
- 17. Reason(s) Display of OMB Expiration Date is Inappropriate..... 11
- 18. Exceptions to Certification for Paperwork Reduction Act Submissions..... 11

## List of Attachments:

- Attachment A – Authorizing Legislation
- Attachment B – Published 60-day FRN
- Attachment C – Interview Guide
- Attachment D – Survey Plan
- Attachment E – Recruitment E-mail for Potential Interview Participants
- Attachment F – Recruitment E-mail for Potential Survey Participants
- Attachment G – Institutional Review Board (IRB) Exemption Letter

- The data from this study will provide guidance to CDC regarding how best to build partnerships with private-sector organizations involved with public health preparedness and response (PHPR).
- This project will provide insights on the incentives, opportunities, barriers, and other characteristics of partnerships that private-sector organizations consider when deciding whether or not to partner with CDC and other public health entities. Upon completion of the project, the research team will generate a final report that includes a fully-developed partnering framework, recommendations, and an example high level implementation plan.
- This study has two data collection components: a series of interviews and one general online survey for decision-makers in all sectors. Interviews will be conducted in person or over the phone and the survey will be conducted using Qualtrics.
- The subpopulations to be studied using the interview campaign and survey are decision-makers in the following sectors: pharmaceutical/life sciences, health IT/mobile, retailers/distributors, academia/research organization, hospital/healthcare provider, health insurance, logistics/transportation, and charitable organization/foundation.
- Interviews will be analyzed using “Voice of the Customer” techniques which focus on deriving stakeholder wants and needs from a service-oriented lens. The semi-quantitative data gathered via the survey (e.g., Likert Scores) will be fairly straightforward and simple numerical measurements (e.g., means, frequencies) will be utilized to illustrate partnership preferences.

## **Supporting Statement Part A: Justification**

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

The Centers for Disease Control (CDC) request a one year clearance from the Office of Management and Budget (OMB) for a new Information Collection Request (ICR) under the Paperwork Reduction Act (PRA) of 1995. This information request will be part of a study that aims to understand and determine how to encourage public-private partnerships (PPP) in the public health preparedness and response (PHPR) space.

The overall project objective is to develop a novel framework, informed by industry and government perspectives and experiences, that CDC and other government public health stakeholders can use to optimally structure public-private partnerships for PHPR activities. The outcomes of this research may be considered generalizable, therefore, this new proposed information collection is required since it is not eligible for generic clearance mechanisms available at CDC. Existing research examining partnerships has focused on providing general principles for partnering between generic organizations, but it has not consistently identified the specific institutional mechanisms and incentives that allow PPPs to succeed across industries. This research is limited when discussing the unique ways in which public-private partnerships operate, and there is little specific guidance regarding what mechanisms should be pursued when combining private and public operations. In addition, existing research provides little guidance regarding what private-sector organizations in varied industries actually prefer when presented with different options for potential partnership structures. Furthermore, little of the existing research is specific to public health preparedness and response and the guidance it provides is not oriented

towards public health practitioners such as CDC program leaders who need actionable, normative, guidance for decision-making.

This project will address these gaps in the literature by collecting information directly from decision-makers in private-sector organizations. The initiative will target those working in the PHPR space and those whose activities, products, and services support public health emergency preparedness (PHEP). The research team will use a series of detailed interviews and a larger survey to identify the specific wants and needs of organizations that currently partner or could potentially partner with CDC in the future. This information will be used to create a final report including a completed partnering framework, recommendations, and example implementation plan, all designed for practical use by program leaders, policymakers, and other practitioners. The findings will be circulated within CDC and shared with other HHS agencies involved in PHEP/PHPR.

Ultimately, this project will provide an effective partnership incentive framework that CDC and other public health stakeholders in the public sector can leverage when building the public-private partnerships necessary to develop and improve PHEP capabilities. It will also allow CDC to enhance its approach to stakeholder collaboration and engagement, and provide actionable goals for public-private partnerships and health system resilience.

The data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241), included in this request as **Attachment A – Authorizing Legislation**.

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

This is a new Information Collection Request (ICR) and this request is not a generic ICR.

This research will allow CDC to more efficiently pursue and achieve some of its most critical objectives. The mission of the Office of Public Health Preparedness and Response (OPHPR) is to strengthen and support the nation's health security in order to save lives and protect against public health threats. This mission is critically dependent on effectively engaging external partners to maximize resources and overall impact during times of emergency. Catastrophic events require the ability to coordinate and leverage all members of the community, including those outside of the government in the private sector and other non-governmental organizations.

Upon completion of the project, the research team will generate a final report that includes a fully-developed partnering framework, specific and actionable recommendations, and an example of a high level implementation plan. This will allow CDC to process and disseminate the information in a timely manner to its internal and external stakeholders. CDC will disseminate the findings through existing internal systems to reach the primary OPHPR and CDC audiences. Possible additional recipients, such as other HHS agencies involved in preparedness and response, will receive the final report or relevant portions of the report via email or hard copy.

The information collected in this study will be used to identify and evaluate: 1) opportunities for partnership with private-sector organizations in industry segments relevant to public health, 2) the various efficiencies that could be achieved via PPPs, 3) any barriers that prevent or could prevent

partnering, and 4) the incentives that CDC could provide to private-sector organizations to encourage relationship building and sustainment. This information will be used in concert with data obtained from literature reviews and interviews with external subject matter experts and internal CDC stakeholders. No existing federal data collections have been used to provide the foundation for this ICR, and the research team does not plan on initiating any additional ICRs for this research project.

Optimizing the OPHPR partnering strategy will enable engagement with new partners, expanded relationships with existing partners, and increased value as a resource for other stakeholders in the preparedness community. This research will provide OPHPR with the overarching strategy and guidance it needs to succeed, and become a leader in this complex field. Without this information, OPHPR may inadvertently miss opportunities to strengthen its partnership network or make unnecessary expenditures where more efficient partnership solutions are possible.

This project has been fully funded as part of BAA 2016-N-17770 under contract number 200-2016-92426.

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

Information technology will be used throughout data collection to reduce the burden on respondents. During the interview portion of data collection, information will be obtained over the telephone or in person, and interview notes will be transcribed into pre-written electronic interview guides. The survey, which will be distributed after the interviews have been completed, will be conducted and analyzed using the online platform Qualtrics, which is secure for use in government projects. The research team will leverage time-saving functionalities available in Qualtrics, such as computer generated skip patterns, to streamline the survey and minimize the time required to complete data collection. Members of the research team will also use leading hardware and software technology to securely store, transfer, and ultimately present the data collected during research proceedings.

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

This novel study aims to systematically evaluate and explore the partnership preferences of private sector organizations, specifically when they are interacting or considering an interaction with government agencies. The research team will only collect data from organizations that work in the PHPR space or whose activities, products, and services could or do support PHEP.

The research team has conducted a literature review and has spoken with external subject matter experts and CDC stakeholders in order to become more familiar with the scientific research and institutional knowledge related to the field. After these activities, the team has concluded that knowledge gaps exist in the public health community regarding PPP best practices for PHPR. The research team is unaware of any alternative data sources that have captured the required information from this specific sample population in the past. As mentioned above, existing research in this area has concentrated on exploring the benefits of partnering between generic organizations, or in other fields unrelated to PHPR. Although examples of successful PPPs in PHPR have been published and disseminated, this information is anecdotal and the generalizability of any observations is unknown. The

research team will utilize this existing research during the study, but the survey and interview campaign will be necessary to understand the nuances of this unique partnership environment.

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

This data collection will not involve small businesses.

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

This request is for two separate information collection initiatives.

The first will be a targeted interview campaign that will seek respondents in the following eight sectors: pharmaceutical/life sciences (n=8), health IT/mobile (n=8), retailers/distributors (n=6), academia/research organization (n=6), hospital/healthcare provider (n=5), health insurance (n=4), logistics/transportation (n=4), and charitable organization/foundation (n=4). The interview questions and the information collected will vary significantly across the different sectors. The second initiative will be a larger survey that will be sent to 200 individuals to reach a total sample population of 100 (assuming a 50% response rate). The interviews and survey will only be administered one time to each individual respondent.

Firstly, both initiatives are necessary because the information gathered during the interviews will support development of the survey questions. For example, the list of incentives in the survey that were initially drawn from background research may be expanded if the research team learns of additional options from interview respondents (**Attachment D – Survey Plan**). Secondly, the format of the two initiatives are conducive to collecting different types of data. The interviews will concentrate on qualitative fact-finding and the exploration of complex issues through dialogue, while the survey will ask specific semi-quantitative and quantitative questions that are answered more efficiently using an online tool (Qualtrics).

Not using both forms of data collection will limit the breadth of understanding that CDC will gain from this exercise. Without both initiatives, CDC may be unable to learn how to better build partnerships with private sector organizations, or it may make unnecessary expenditures where more efficient partnership solutions are a possibility.

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

This request fully complies with the regulation 5 CFR 1320.5

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

**A:** A 60-day Federal Register Notice was published in the *Federal Register* on April 27, 2017, vol. 82, No.80, pp. 19368 (see **Attachment B – Published 60-day FRN**).

One comment was received (**Attachment B1**). CDC provided a standard response to the commenter.

**B:** Consultations outside of CDC did not occur.

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

Respondents will not be offered any incentives for their participation in surveys or interviews.

## 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

OPHPR determined that the Privacy Act is not applicable to this information collection. The proposed information collection will not involve collecting or sharing respondents' personal identification or place of residence. No personal identifiable information will be collected or retained. No information can be retrieved by name of the respondent. Individuals will be responding to the information collection completely voluntarily. Only de-identified data will be received by OPHPR.

The contractor will collect and analyze the project specific data. OPHPR will provide technical assistance in the design, implementation, and analysis of the project but will not be in contact with project participants (and will not have access to any personally identifiable information). All information provided by participants will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Participants will be informed prior to participation that their responses will be treated in a secure manner.

OPHPR, contractors, and the contractor organizations will follow procedures for securing and maintaining privacy during all stages of information collection.

Participants will be advised of the nature of the information collection activity, the length of time it will require, and that participation is purely voluntary. Participants will be assured that no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions. The exact language used to convey this information is provided in the data collection materials (**Attachments C and D**) and in the recruitment letters (**Attachments E and F**). Participants will provide informed consent verbally at the start of all interviews (**Attachment C**) and will indicate their informed consent electronically prior to starting the online survey (**Attachment D**).

All data will be stored in secure electronic files maintained by the contractor and will be accessible only to staff directly involved in the project. All members of the project will be required to sign a statement pledging their personal commitment to guarding the security of collected information. Online information collections will conform completely to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987]; all information will be maintained in a password protected secure location. Stored transcripts will not contain personally identifiable information.

No system of records is being created for this information collection. No personal identifiable information will be collected or retained.

The proposed collection will not impact the respondents' privacy. All collected information will remain secure. Collected information including interview transcripts will be entered into appropriate data management systems and will not be linkable to personally identifiable information. Final electronic

data (transcripts and summary reports) will be maintained by OPHPR. Analysis and resulting publications will not include any personal identifying information.

### 11. Institution Review Board (IRB) and Justification for Sensitive Questions

An Institutional Review Board (IRB) review was not required for this study. An IRB Exemption Letter is included as **Attachment G**.

The research team does not plan to ask any potentially sensitive personal questions during the interviews or during the survey. Respondents will be asked questions about the organizations where they are employed, but the disclosure of this non-sensitive information should not result in liability or competitive disadvantage to their organization. Respondents will also have the option, and will be informed that they have the option, to skip any questions that they feel uncomfortable answering.

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

This project has two data collection components. The first will be an interview campaign conducted by the research team with decision-makers at private sector organizations across eight industry groups involved in the PHPR space. The second will consist of a single standard online Public-Private Partnership Survey (PPP Survey) for all decision-makers across all industries. The survey will be conducted using the software platform Qualtrics. All data collection will be completed within a single year after OMB approval, therefore the numbers below are all total numbers and have not been annualized over a multi-year period.

**Exhibits 1 and 2** summarize the estimated annualized burden in hours and estimated cost that both data collection activities will require. The time estimates are based on the past experiences of the research team in similar data collection situations. All hourly wages are taken from data provided by the U.S. Department of Labor's Bureau of Labor Statistics. The details for the interview campaign are summarized in the first line of **Exhibits 1 and 2**, and the information for the online survey is provided in the second line. The research team will continue to contact new potential interviewees until the target sample size of 45 is met for the interview campaign. The research team anticipates a response rate of approximately 50% for the survey and plans to contact 200 individuals to reach an overall survey sample population of 100 respondents.

#### Exhibit 1: Estimated Annualized Burden Hours

Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Private Sector Organization Senior Leaders	Interview Guide	45	1	1	45
Private Sector Organization Manager	Survey Plan	100	1	15/60	25
<b>Total</b>		<b>145</b>			<b>70</b>

**Exhibit 2: Estimated Annualized Burden Costs**

Respondents	Form Name	Total Burden Hours (in hours)	Hourly Wage Rate	Total Respondent Costs
Private Sector Organization Senior Leaders	Interview Guide	45	\$89.35	\$4,020.75
Private Sector Organization Manager	Survey Plan	25	\$57.44	\$1,436.00
<b>Total</b>		<b>70</b>		<b>\$5,456.75</b>

The total anticipated burden of the data collection activities for this study is 70 hours and the total estimated burden cost of data collection is \$5,456.75.

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

There are no other cost burdens to respondents or record keepers for this data collection.

**14. Annualized Cost to the Federal Government**

The government will pay PwC \$698,587.88 over 2 years to perform the research tasks outlined in this document. The cost of the salary and benefits for the federal employees involved in oversight of the PwC team and direct collaboration on the project has been estimated at \$18,380 over 2 years. Therefore the total annualized cost to the federal government to complete this project is **\$358,484** (\$716,968 over 2 years).

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

This is a new data/information collection.

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

Exhibit 3 outlines the timeline for the activities related to this data collection initiative.

**Exhibit 3. Project Timeline**

Activity	Time Schedule
Recruitment of Interview Respondents	0-6 months after OMB approval
Data Collection (Interviews)	0-6 months after OMB approval
Recruitment of Survey Respondents	3-4 months after OMB approval
Data Collection (Surveys)	3-4 months after OMB approval
Analysis	4-6 months after OMB approval
Completion of Final Report	6 months after OMB approval

Interviews will be structured and analyzed using “Voice of the Customer” techniques which focus on deriving stakeholder wants and needs from a service-oriented lens. The research team will read and discuss all the consolidated interview transcripts and identify repeated themes and consistent observations from the respondents within the various industry groups.

The survey will measure how different organizations view different partnership opportunities, barriers, incentives, efficiencies in a rigorous semi-quantitative manner (e.g., using Likert scales). Because the quantitative data will be fairly straightforward, only simple numerical analysis (means, frequencies of certain responses etc.) will be utilized and provided in the final report. The results of the survey will be analyzed and presented at the industry level (e.g., all the pharmaceutical and life sciences companies will have their responses aggregated and presented together). This will allow the specific partnership preferences of different types of organizations to be illustrated and compared.

**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.