**GenIC Clearance for CDC/ATSDR**

**Formative Research and Tool Development**

**Clinician Preferences for CDC Clinical Guidelines**

### OMB Control No. 0920-1154

#### November 16, 2018

#### Supporting Statement A

**Contact:**

Colleen Brouillette

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

1600 Clifton Road, NE

Atlanta, Georgia 30333

Phone: (404) 718-5208

Email: mfi3@cdc.gov

#### Table of Contents

[1. Circumstances Making the Collection of Information Necessary 3](#_Toc473880017)

[2. Purpose and Use of Information Collection 3](#_Toc473880018)

[3. Use of Improved Information Technology and Burden Reduction 3](#_Toc473880019)

[4. Efforts to Identify Duplication and Use of Similar Information 4](#_Toc473880020)

[5. Impact on Small Businesses or Other Small Entities 4](#_Toc473880021)

[6. Consequences of Collecting the Information Less Frequently 4](#_Toc473880022)

[7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5 4](#_Toc473880023)

[8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency 4](#_Toc473880024)

[9. Explanation of Any Payment or Gift to Respondents 4](#_Toc473880025)

[10. Protection of the Privacy and Confidentiality of Information Provided by Respondents 4](#_Toc473880026)

[11. Institutional Review Board (IRB) and Justification for Sensitive Questions 5](#_Toc473880027)

[12. Estimates of Annualized Burden Hours and Costs 5](#_Toc473880028)

[13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers 6](#_Toc473880029)

[14. Annualized Cost to the Government 6](#_Toc473880030)

[15. Explanation for Program Changes or Adjustments 6](#_Toc473880031)

[16. Plans for Tabulation and Publication and Project Time Schedule 6](#_Toc473880032)

[17. Reason(s) Display of OMB Expiration Date is Inappropriate 6](#_Toc473880033)

[18. Exceptions to Certification for Paperwork Reduction Act Submissions 6](#_Toc473880034)

[Attachments 7](#_Toc473880035)

* **Goal of the study:** To identify the preferences of clinicians for CDC clinical guidance on infectious diseases, including its location and format, as well as their preferences for how they are alerted to the publication or updating of guidance. The project also seeks to assess any differences in preferences for guidance for routine care and guidance for use during public health emergencies.
* **Intended use of the resulting data:** to internally inform the development and dissemination of future CDC clinical guidelines for infectious diseases.
* **Methods to be used to collect:** One-on-one telephone interviews with a random sampling of specific physician types from across the United States.
* **The subpopulation to be studied:** Interviewees include family and general practitioners, OBGYNs, and pediatricians of varying levels of practice and geographic representation.
* **How data will be analyzed:** Descriptive analyses and thematic analysis of qualitative interview data.

# Circumstances Making the Collection of Information Necessary

Clinical guidelines provide essential information for the diagnosis and treatment of infectious diseases. To ensure clinicians receive and implement these guidelines, CDC’s clinical guidelines should be presented in an understandable and easy to use format and be found in a location easily accessible and useable by clinicians in their daily practice. Clinicians must also know when new guidance is published or existing guidance is updated in order to provide the best care for their patients. Conducting one-on-one in-depth interviews with physicians will provide valuable insights into how CDC can most effectively develop, disseminate, and communicate about clinical guidelines for infectious diseases in routine and publish health emergency settings.

For this reason, the Centers for Disease Control and Prevention (CDC) requests approval for a new Gen-IC, “Clinician Preferences for CDC Clinical Guidelines” under OMB Control No. 0920-1154.

# Purpose and Use of Information Collection

The purpose of this project, and the goals of each one-on-one interview, is to identify the preferences of clinicians for CDC clinical guidance on infectious diseases, including its location and format, as well as their preferences for how they are alerted to the publication or updating of guidance. The project also seeks to assess any differences in preferences for guidance for routine care and guidance for use during public health emergencies. Information collected will be used by CDC to inform future develop, disseminate, and communicate about clinical guidelines.

Deloitte Consulting will conduct all interviews during this formative research project, with guidance from CDC. Deloitte Consulting will subcontract the recruitment activities to another vendor. Data collection will involve recruiting and screening (Attachment 2) no more than 25 respondents and conducting one-on-one phone interviews that will last no more than 60-minutes.

# Use of Improved Information Technology and Burden Reduction

Data will be collected via one-on-one phone interviews conducted by Deloitte Consulting. A note taker will be listening to the conversation to take notes during each interview. Other CDC and Deloitte staff will listen as well. All interviews will be audio recorded to ensure participant responses are captured accurately. The recordings will be transcribed and personal identifiable information (PII) removed. Recordings will be destroyed. Questions in the interview facilitator guide (Attachment 1) have been limited to only those relevant to the target audience to reduce burden on respondents.

A total of 25 eligible physicians from the following subpopulations will be recruited: nine family or general practice physicians, eight OB/GYNs, and eight pediatricians.

# Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of the availability of any other qualitative data collection activities specific to preferences for CDC clinical guidance; however, this project builds upon the knowledge gained from a previous unpublished quantitative electronic survey sent to a national sampling of physicians. The in-depth interviews from this project will delve deeper into some of the findings from the survey.

# Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

# Consequences of Collecting the Information Less Frequently

This is a one-time information collection.

# Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A *Federal Register* notice was published for this generic package on July 18, 2016, Vol. 81, No. 137, pp. 46680. No public comments were received.

B. No consultations outside of CDC will take place as the project is to inform internal activities.

# Explanation of Any Payment or Gift to Respondents

For this research effort, approval is requested for a monetary token of appreciation valued at $75 for all participating physicians. This will likely be delivered as a gift card provided through the recruitment sub-contractor. The $75 amount was determined on three factors: (1) limited incentives represent a significant challenge to the timeline because of the challenge it creates to recruit physician participants which in turn affects our timeline; (2) the research focus on clinical guidelines requires research with specific healthcare provider respondents – specifically with practicing physicians; and (3) difficulties experienced in recruiting with low incentives.

Factor 1: Lower incentives represent a significant challenge to the overall timeline of the clinical guidelines research effort. The project team has limited time to conduct these in-depth interviews in order to obtain results before the expiration of the contract with Deloitte who will be facilitating the interviews.

* Based on prior experience, (and per discussion with multiple recruitment firms) approximately $200 is needed for physicians to incentivize their participation in research efforts. This number is based on average billable rates that physicians charge for their consulting services. Given budget restraints, we ask for $75 in hopes that providing a percentage of their typical billable rate will incentivize them more than no incentive at all. From experience, lower incentives make recruiting these specialized audiences exceptionally difficult and increase the amount of time needed for recruitment and data collection. Increasing the time for the research will jeopardize the ability to conduct the research and place the project in its entirety at risk.

Factor 2: The focus on clinical guidelines for the research project requires recruit of very specific types of healthcare providers. It is critical that these specific types of physicians are recruited to participate as they are most likely to receive and implement clinical guidelines for diagnosis and treatment of patients in both regular and public health emergency settings. The specific healthcare provider types are those who CDC feels are critical to reach in order to educate and share the latest clinical guidelines and have them implemented in practice.

* Specific types of healthcare providers are required for this research, including pediatricians, OBGYNs, general and family practitioners. These types of providers are notably difficult to recruit due to overwhelming requests for their participation in research and their busy schedules, and because they often serve in primary care roles caring for patients in busy practices. From experience, higher incentives are needed to recruit these audiences to participate in research.
* The project’s screening criteria intentionally narrow the participant pool to ensure that we recruit physicians most likely to use CDC clinical guidance.
* Because clinical guidelines will vary based on the infectious disease or the public health emergency, the project requires a sample of physicians from across the United States. These must be working physicians and as such they will lose billable patient time by participating in our research study. Providing the request monetary token of appreciation will help lessen the financial burden for the participants.

Factor 3: In previous unrelated research efforts with a similar target audience, Deloitte experienced many difficulties recruiting the target physicians. This indicates the need for a higher amount as a token of appreciation for participation in this research.

* From past experiences, these groups of physician types are frequently inundated with requests to participate in interviews or surveys. As a result, they often decline to participate or they cancel at the last minute due to patient load or work obligations. Based on research and experience, a low token of appreciation amount hampers recruiting to this type of research because it fails to motivate these groups to participate due to the demands of their work schedules, professional commitments, and patient loads. From conversations with market recruiting firms, typical incentives range from $150 - $300 for 60 minutes of time depending on the physician type.
* Because this interview will be conducted via phone, there is no travel required, but it may last up to one hour, costing the participant billable patient time, a $75 token of appreciation is requested.

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

Data will be collected via one-on-one phone interviews conducted by Deloitte Consulting. All interviews will be audio recorded to ensure participant responses are captured accurately. The recordings will be transcribed and all personal identifiable information (PII) mentioned (names, places of work, etc.) will be removed. Recordings will be destroyed. All files delivered to CDC will have PII removed so no participant can be linked to their responses.

# Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID’s Human Subjects Advisor has determined that information collection is not research involving human subjects (Attachment 3). IRB approval is not required.

Justification for Sensitive Questions

There are no planned sensitive questions.

# Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The burden of collection will be 1 hour of time for each participant, for a total of 25 hours. The burden was determined by totaling the individual and cumulative amount of interview time the project will take. The 25 interviews will only be conducted once, so the annual burden is the same 25 hours.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
| General Practice/Family Physicians | Clinical Guidance Interview Guide | 9 | 1 | 1 | 9 |
| OB/GYN Physicians | Clinical Guidance Interview Guide | 8 | 1 | 1 | 8 |
| Pediatricians | Clinical Guidance Interview Guide | 8 | 1 | 1 | 8 |
|  | **Total** | 25 hours |

B. Estimated Annualized Burden Costs

The [Department of Labor website](https://www.bls.gov/oes/current/oes_nat.htm) was used to determine appropriate wage rates for each specific type of respondents.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
| Family & General Practitioners | Clinical Guidance Interview Guide | 9 | $100.27 | $902.43 |
| Obstetricians/Gynecologists | Clinical Guidance Interview Guide | 8 | $113.10 | $904.80 |
| Pediatricians | Clinical Guidance Interview Guide | 8 | $90.16 | $721.28 |
| **Total** |  | $2,528.51 |

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

There are no costs to respondents other than their time to participate.

# Annualized Cost to the Government

The hourly wage for the CDC employee that will observe and provide feedback during all interviews was used to calculate the burden. Operational costs will be covered by Deloitte Consulting via funds added to a previously awarded contract in the amount of $158,172.94. There will be no additional expenses incurred without this collection.

|  |
| --- |
| Estimated Annualized Cost to the Government per Activity |
| Cost Category | Estimated Annualized Cost |
| GS-13 Health Communication Specialist | $1,207.50  |
|  |  |

# Explanation for Program Changes or Adjustments

# No change in burden is requested as this is a new information collection.

# Plans for Tabulation and Publication and Project Time Schedule

|  |
| --- |
| **Project Time Schedule** |
| **Activity** | **Time Schedule** |
| Recruit Respondents | January 2019- February 2019 |
| Conduct Interviews to Collect Information | February – March 2019 |
| Analyze Interview Results and Draft Report | April – May 2019 |

# Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

# Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

# Attachments

1. Clinical Guidance Interview Guide
2. Clinician Guidelines Interview Screening Instrument
3. Non-research Determination