Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease

Request for OMB approval of an Emergency ICR

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Supporting Statement A

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Table of Contents

- **Goals:** Determine knowledge, attitudes, and practices (KAPs) related to a new Domestic Readiness Initiative on Zika Virus Disease being launched in select regions of the United States (U.S.) mainland and Puerto Rico.
- **Intended Use:** Improve planning, implementation, refinement, and demonstrate outcomes of a Zika Domestic Readiness Initiative communication and education effort.
- **Methods:** Conduct random-digit dial telephone surveys via computer-assisted telephone interviewing (CATI); conduct direct recruitment via telephone using both landline and cell phone numbers.
- **Subpopulation:** Target participants include residents of 20 states (AL, AR, AZ, CA, FL, GA, HI, IL, LA, MD, MA, MS, NJ, NM, NY, NC, SC, TN, TX, and VA) and Washington D.C. most likely impacted by Zika virus disease if the U.S. domestically and Puerto Rico, a U.S. territory already severely impacted by Zika.
- **Data Analysis:** Descriptive statistics of survey data will be performed using a quantitative software package (SAS).

This is an emergency request for a new information collection for six months. This ICR includes a telephone survey, which is part of CDC's ongoing response in Puerto Rico and the domestic U.S. to the Zika virus outbreak. Information collection is expected to begin once approved. Since data collection is planned to last six months, a formal ICR will be submitted to OMB in order to continue information collection beyond that time frame.

PART A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Zika virus is transmitted through *Aedes aegypti* mosquito bites, a pregnant woman to her child, sex, blood transfusion and laboratory exposure (1). Zika virus can be spread from a pregnant woman to her fetus, and have detrimental effects causing microcephaly and other birth defects (2). Additionally, in a small proportion of adults, Zika can cause Guillain-Barré syndrome, a nerve disease that can cause temporary or permanent paralysis (3). On February 1st 2016, the World Health Organization (WHO) declared Zika virus a public health emergency of international concern (PHEIC) because of clusters of microcephaly and other neurological disorders in babies born in some areas affected by Zika. On February 5th, CDC updated its guidelines to include women residing in areas with local Zika virus transmission, and expanded its recommendations to offer testing to asymptomatic women with possible Zika virus exposure.

Since late 2015, Zika has rapidly spread through Puerto Rico. As of July 2016, there have been 7,286 confirmed cases of Zika in Puerto Rico, with 788 cases among pregnant women and 23

cases of Guillain-Barré caused by Zika (4). In the continental United States, there have been 1,658 travel-associated cases of Zika. And as of August 2nd, there have been 14 locally-acquired Zika cases in Miami, Florida (5). Due to the urgent nature of this public health emergency, CDC is implementing a Zika prevention communication and education initiative in the continental United States and Puerto Rico.

By launching a Domestic Readiness Initiative on Zika health protection and communication, CDC intends to reach audiences with accurate information regarding Zika and motivate them to follow recommended actions to protect themselves. The overall objective of this project is to launch a Zika health protection and communication campaign in response to a growing public health emergency. The campaign supports the public health goal of preventing as many Zika-related complications and negative outcomes as possible.

The campaign will be conducted in two regions, based on evolving epidemiological data. The campaign roll-out will occur in: 1) the Commonwealth of Puerto Rico and 2) twenty US states with historical presence of *Aedes aegypti* mosquitoes and other contributing factors (AL, AR, AZ, CA, FL, GA, HI, IL, LA, MD, MA, MS, NJ, NM, NY, NC, SC, TN, TX, VA) and DC.

The Centers for Disease Control and Prevention (CDC) requests approval from the Office of Management and Budget (OMB) to conduct an assessment of a domestic U.S. and Puerto Rico-based communication and education initiative aimed at encouraging at-risk populations to prepare and protect themselves and their families from Zika virus infection. As part of the mission of CDC's Domestic Readiness Initiative on the Zika Virus Disease, CDC will assess the following communication and education objectives: 1) determine the reach and saturation of the initiative's messages in Puerto Rico and 20 U.S. states and Washington, DC; 2) measure the extent to which messages were communicated clearly across multiple channels to advance knowledge and counter misinformation; and 3) monitor individual and community-level awareness, attitudes and intention to follow recommended behaviors.

CDC is authorized to collect these data under the Public Health Service Act (42 USC 41), Section 301 (Attachment A). The information collection for which approval is sought is in accordance with CDC's mission, as the nation's health protection agency, to save lives and protect people from health threats. To accomplish this mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

2. Purpose and Use of Information Collection

The purpose of this data collection is to conduct a timely assessment of communication and education efforts to prepare and protect populations at risk of contracting the Zika virus in the domestic U.S and Puerto Rico. This data collection includes a single, cross-sectional survey implemented at three points in time – during the initial launch of a new Zika Readiness communication and education initiative, 3-months post-launch to assess short term outcomes of the initiative and 12 months post-launch to assess longer term outcomes of the initiative.

The primary use of the collected information will be to inform an outcome evaluation that will determine the extent to which the campaign affects awareness, attitudes and intention to follow

recommended behaviors at different points during the campaign. The goal of the evaluation is to better understand awareness of campaign activities, how people perceive Zika as a health risk, and assess their uptake of recommended health behaviors, such as applying insect repellent, using condoms, and wearing long-sleeved clothing. As education and campaign materials are rolled out across the 20 states and Washington DC, they are expected to have an increasing and consistent effect on key outcome variables. Sample size calculations are based on this primary use of the data.

Secondarily, the data will be used to inform the process evaluation that will determine the reach of the initiative's messages and assess the extent to which messages were communicated clearly across multiple channels. Questions included in the survey, such as 'Where have you heard information about how to protect yourself from Zika?' and 'Thinking about the past 30 days, how often have you seen, read or heard information about how to protect yourself from Zika?' will allow adjustments, if needed, to the development and dissemination of the campaign materials. Process evaluation data will be used to enhance and revise existing materials and implementation plans. While the process evaluation data may be analyzed by target group, such as pregnant women, this is not the primary purpose of this data collection nor have sample sizes been calculated to address process or outcome measures by subgroup. Subgroup analyses on the process evaluation data will be used for informational purposes only to provide timely data on campaign implementation and will not be assumed to be representative of the larger population. Additionally, these data may offer lessons learned to inform future communications on infectious disease outbreaks.

Infectious disease outbreaks, like Zika, can have profound health consequences. When the unexpected occurs, people immediately want to know how to respond, recover, and protect themselves, their families, and their communities. Clear and accurate communication that prompts appropriate action during an emergency is essential to reduce injury, illness, and suffering, and to save lives. In this request for Emergency ICR clearance, the CDC is responding to a situation where normal clearance procedures are reasonably likely to prevent or disrupt the collection of information, and public harm could reasonably result if normal clearance procedures are followed.

3. Use of Improved Information Technology and Burden Reduction

This information request is in compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. The method to be utilized for data collection in this assessment will be phone interviews that will be directly entered into an online CATI system in order to eliminate respondent burden in answering paper questionnaires and aid in data processing and reporting efficiency. In all information collections, the number of questions posed will be held to the minimum required in order to elicit the necessary data.

4. Efforts to Identify Duplication and Use of Similar Information

Because of the novelty of Zika virus in the domestic U.S. and Puerto Rico and the specific focus of the data collection on the outcomes of a new communication and education initiative being launched by CDC in August 2016, no other agency is anticipated to be collecting similar data. The proposed assessment will allow CDC to significantly improve its ability to develop, refine and monitor communication and education activities as the initiative evolves. The results and final products from these activities may be used by multiple government and non-profit agencies.

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 random digit dial telephone survey at three points in time to assess knowledge, attitudes, and behaviors of Zika virus prevention at the outset of disease exposure and through the course of disease development and viral spread across the country. There are no legal obstacles to reduce the burden.

According to the CDC's Introduction to Program Evaluation for Public Health Programs, monitoring is critical for engaging in scientifically sound communication and educational efforts. Evaluation provides accountability to stakeholder's for CDC's activities by demonstrating the effectiveness and the impact of their communication, training, and educational activities (5). Evaluation improves the effectiveness and efficiency of existing programs and supports the most effective distribution of resources.

If this information is not collected, CDC's ability to effectively communicate messages to populations at highest risk for the Zika virus in the domestic U.S. and Puerto Rico may lead to increased exposure to Zika and significant health impacts, including morbidity and mortality, among these groups. Furthermore, if these communication and education efforts are not tested, then valuable resources could be expended without evidence that the activity is appropriate or effective.

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

There are no special circumstances with this information. 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 will be published at the time of the collection's approval to notify the public of the Emergency ICR activities and request public comment. A 60-day Federal Register Notice is included as Attachment B.

B. Communication partners, both domestically in the US and in Puerto Rico, have provided information on dissemination channels to be included in the development of the survey.

9. Explanation of Any Payment or Gift to Respondents

No remuneration or incentive will be provided to participants.

10. Assurance of Confidentiality Provided to Respondents

This information collection has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases, and it has been determined that the Privacy Act does not apply. No personally identifiable information is being collected.

The contractor will not collect information in identifiable form. All of the survey data will be collected over the phone and will be entered directly into a computer-assisted telephone interviewing (CATI) system. Data will be stored on the contractor's secure server. During recruiting, telephone numbers of potential and actual participants will be collected via the random digit dialing system to facilitate participation. These data will be maintained locally in the secure online scheduler of which only local research staff will have access. This system will not be linked to the screening or individual interview data in any way that could connect a participant's identity to his/her responses. The number of staff with access to this information will be kept at the minimum necessary. Contact information for study participants will be destroyed after recruitment is completed.

Personally identifying information will not be included with study data and will not be transmitted to the CDC or any other agency. CDC staff will not have access to any identifying information. All data will be transmitted to CDC via a secure data network. De-identified study data will be maintained at the site and CDC indefinitely.

CDC will follow procedures for ensuring and maintaining privacy during all stages of data collection. Respondents will be informed prior to participation that information collected will be kept confidential and procedures to protect data will be strictly followed. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. The data collected will be retained for five years, which exceeds the minimum outlined in Federal IRB regulations. This will enable CDC to refer to previous data if similar projects are conducted in the future.

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

The CDC Human Research Subject Officer has determined that the CDC Domestic Readiness Initiative on Zika Virus Disease Monitoring Plan is exempt under 45 CFR 46.101(b)(2). The determination is valid for three years through 7/12/2019. (See Attachment C--IRB Determination).

Participants will be asked questions pertaining to safe sexual behavior, such as if they are consistently and correctly use condoms when having sex, if they are currently avoiding having sex, or if they have had unprotected sex in the last six months. As the Zika virus is known to be transmitted sexually, it is important that safe sexual behaviors, and motivations behind these behaviors are well understood in at-risk populations. To minimize psychological distress, the interviewer will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time.

12. Estimates of Annualized Burden Hours and Costs

A. The average burden for each respondent will be approximately 12 minutes per survey. The survey will be conducted at three points in time using random digit dialing (each time with a new population). In the domestic U.S., the questionnaire (Attachment D – Zika Readiness Initiative Survey (English); Attachment E – Zika Readiness Initiative Survey (Spanish)) will be administered to 1) 1200 participants immediately following OMB approval and near the launch of a new Zika Readiness communication and education initiative (expected September 2016), 2) 1200 participants 3-months post-launch of the initiative to assess short term outcomes, and 3) a final group of 1200 participants 12-months post-launch of the initiative to assess longer term outcomes for a total of 3600 participants in the domestic U.S. As shown in Table 12.A, the same approach will be used in Puerto Rico. It is estimated that the total burden across both respondent types will be 1,440 hours.

Table 12.A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
U.S. Domestic Adults	Zika Readiness Initiative Survey	3600	1	12/60	720
Puerto Rico Adults	Zika Readiness Initiative Survey	3600	1	12/60	720
TOTAL		7200			1,440

B. Table 12.B presents the calculations for cost of respondents' time using U.S. Hourly mean wage information from the U.S. Department of Labor's Bureau of Labor Statistics

website (http://www.bls.gov/oes/current/oes_nat.htm), specifically originating from the 2015 National Occupational Employment and Wage Estimates. Based on DOL data for all types of jobs/careers, an average hourly wage of $23.23 is estimated for all respondents. The total estimated annualized respondent cost is $33,452.

Table 12.B: Estimated Annualized Burden Hours

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents' Costs
U.S. Domestic Adults	Zika Readiness Initiative Survey	720	$23.23	$16,726
Puerto Rico Adults	Zika Readiness Initiative Survey	720	$23.23	$16,726
TOTAL	**--**	**1440**	**$23.23**	**$33,452**

13. Estimates of Other 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 the survey.

14. Annualized Cost to the Government

The project will span 16 months, beginning in May 2016 and ending in late 2017. The total estimated cost to the Federal Government for the *CDC Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease* data collection activity is $72,922. This includes the cost of development the survey and initiated the random digit dialing program, conducting the interviews, and analyzing the interview responses ($44,922) plus 20% of a GS-15 CDC employee's time at $140,000 annual salary ($28,000).

Table 14: Estimated Annualized Cost to the Federal Government

Year	Contractor	CDC	Total
2016	$22,461	$14,000	$36,461
2017	$22,461	$14,000	$36,461
TOTAL			$72,922

15. Explanation for Program Changes or Adjustments

This is a new information collection request, therefore program changes and adjustments do not apply at this time

16. Plans for Tabulation and Publication and Project Time Schedule

Under the guidance and direction of the CDC, the contractor will conduct analyses of interview responses. The primary use of the study's outcomes will be for both process and outcome evaluation purposes. The first round of cross-sectional surveys will be assessed to inform on-going campaign planning, including but not limited to, adjustments of how prevention methods are presented and modifications to campaign dissemination. It will also be used as a baseline to future assessment of campaign outcomes. The cross-sectional surveys administered at 3-months and 12-months after the campaign launches will allow for continued assessment of campaign planning as well as short term (3-month) and long-term (12-months) changes in knowledge, attitudes and behavioral intention to adopt recommended behaviors to protect against Zika virus. An interim report will be prepared following the first two phases of data collection: the initial survey immediately following OMB approval and 3 months post-launch of the communication and education materials. A final report will be prepared following the completion of data collection. The final report will be structured similarly to the interim reports, however it will present additional analyses that are possible once all data are collected. The project schedule is as follows:

Table 16: Project Schedule

Activity	Time Schedule
Develop protocol, data collection tools, IRB and OMB application, submit materials for clearance	Prior and during OMB clearance period
Initial survey: First wave of random digit dialing interviews in the domestic US and Puerto Rico	1 month after OMB approval
Interim Report to CDC	3 months after OMB approval
3-months post-launch survey: Second wave of random digit dialing interviews in the domestic US and Puerto Rico	3 months after OMB approval
Interim Report to CDC	9 months after OMB approval
12-months post-launch survey: Third wave of random digit dialing interviews in the domestic US and Puerto Rico	12 months after OMB approval
Complete data analysis	14 months after OMB approval
Final report and recommendations to CDC	16 months after OMB approval

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

No exemption is being requested. The display of the expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

(1) *Zika Virus: Transmission & Risks*. (2016, July 25). Retrieved August 2, 2016, from CDC: http://www.cdc.gov/zika/transmission/index.html

(2) Rasmussen SA, Jamieson DJ, Honein MA, Petersen LR. Zika virus and birth defects—reviewing the evidence for causality. N Engl J Med 2016;374:1981–7. CrossRef PubMed

(3) *Zika and Guillain-Barré Syndrome*. (2016, August 1). Retrieved August 3, 2016, from CDC: http://www.cdc.gov/zika/about/gbs-qa.html

(4) Puerto Rico Departamento de Salud. (2016, Julio 28). Informe Semanal de Enfermedades Arbovirales- Semana 28 (8 al 14 de Julio de 2016).

(5) Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide, 2011, available at: http://www.cdc.gov/eval/guide/

ATTACHMENTS

Note: Attachments are included as separate files as instructed.

Attachment A – Public Health Service Act (42 USC 241), Section 301

Attachment B – 60 Day Notice

Attachment C - IRB Determination Letter of Exemption

Attachment D - Zika Readiness Initiative Survey – English

Attachment E – Zika Readiness Initiative Survey - Spanish