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

Request for OMB approval of ICR

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Supporting Statement A

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- **Goals:** Determine knowledge, attitudes, and practices (KAPs) related to a Domestic Readiness Initiative on Zika Virus Disease being launched in two phases in select regions of the United States (U.S.) mainland and Puerto Rico. This is not a duplicative data collection effort.

- **Intended Use**: Improve planning, implementation, and refinements of possible future campaign activities; demonstrate outcomes of a Zika Domestic Readiness Initiative communication and education effort being launched in two phases

- **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 four locations of differing levels of campaign activities: Puerto Rico; Miami, FL; Houston, TX; and Mississippi.

- **Data Analysis:** Descriptive statistics of survey data will be performed using a quantitative software package (SAS).

The fundamental objective of the evaluation is to measure the reach and effectiveness of the Zika health protection and communication campaign. This includes the uptake of behavioral preventive action messages as evidenced by appropriate behavior change measures and a quantitative assessment of the absorption and sharing of the campaign's education information. The proposed study design is structured around three survey waves: an initial survey during the first phase of the campaign (wave 1 completed in October/November 2016); a mid-point assessment survey (wave 2 completed in February/March 2017); and a final measurement survey conducted at a concluding point in time following the second phase of the campaign (wave 3 planned for September 2017). This evaluation design is intended to capture differences among the varying campaign levels and across time. ***The current Information Collection Request submitted for approval is to complete the final data collection for this campaign (wave 3). Waves 1 and 2 were approved by OMB and completed last year under a separate, emergency information collection request (OMB control no. 0920-1136).*** Wave 3 data will be collected following full implementation of both phases of the campaign and, as such, will be the only data available upon which to determine the full reach and effectiveness collectively of all campaign efforts over time. The Wave 3 data is, therefore, imperative for determining whether prolonged exposure to the campaign impacted knowledge, attitudes and protective actions as prescribed or whether additional communication efforts are necessary to not only protect populations vulnerable to the harmful health effects of the Zika virus, but to ensure good stewardship of resources.

CDC seeks to gain OMB approval of this new information collection request to conduct a final survey (wave 3) evaluating the CDC Domestic Readiness Initiative for Zika Virus. The Zika Readiness Initiative campaign has been implemented in two phases with peak campaign activity coinciding with the height of mosquito season during the summer months of 2016 (phase 1) and 2017 (phase 2). The initial evaluation design was structured around three survey waves as follows: 1) a survey conducted during the first phase of the campaign, 2) a mid-point assessment survey, and 3) a final measurement survey at a concluding point in time following the second phase of the campaign. ICR emergency approval was granted in 2016 (OMB control no. 0920-1136, expiration 3/31/17) to conduct the first two waves of data collection which captured the effectiveness of the first phase of the campaign. Survey wave 1 was conducted in October/November of 2016, and survey wave 2 was conducted in February/March of 2017. The third wave of data collection will allow CDC to capture the effectiveness of the second phase of the campaign being implemented through late summer/early fall 2017. While the campaign objectives and the call to action remain the same across both phases, campaign materials have been modified between phases based the first two waves of data collection to better address misinformation about Zika and promote a sense of urgency to adopt preventive actions. The third and final wave of data collection is vital to CDC's continued understanding of how the campaign information is received by target audiences and what actions are being taken to prevent Zika virus transmission after prolonged exposure to the campaign. The three waves together are the complete evaluation design for this communications effort. Findings will be used to improve implementation, refinements and demonstrate outcomes of a Zika Domestic Readiness Initiative communication and education effort.

Following the same methodology as the first two waves, the third wave of data collection will include 600 respondents at each of four locations with differing levels of campaign activity, for a total of 2400 interviews.

The four targeted geographic locations can be described as follows:

1. an area that has had an intense, long-running active campaign, of which the Island of **Puerto Rico** is the only such location
2. a current intense active campaign that has been taking place in the **Miami DMA** (designated market area)
3. a newer campaign area with mass media plus digital of which the **Houston DMA** is typified as representing, and,
4. a control area that currently has had no significant campaign efforts implemented and of which the state of **Mississippi** would represent.

The interviews per wave are distributed equally across these four areas. This balanced, rectangular evaluation design is intended to capture differences among the differing campaign levels and differences across time.

PART A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Zika virus is transmitted through primarily *Aedes aegypti* but also *Aedes albopictus* mosquito bites, from a pregnant woman to her child, through sex, via a blood transfusion and through 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, 2016, the Centers for Disease Control and Prevention (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 November 2016, there have been 35,136 confirmed cases of Zika in Puerto Rico, with 2,797 cases among pregnant women and 67 cases of Guillain-Barré caused by Zika (4). In the continental United States, there have been 4,432 travel-associated cases of Zika and 185 locally-acquired Zika cases in Florida and Texas (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.

Based on evolving epidemiological data, campaign roll-out across both phases will occur in1) the Commonwealth of Puerto Rico and 2) several US states with significant probability of experiencing a Zika outbreak based on historical presence of *Aedes aegypti* or *Aedes albopictus* mosquitoes and other contributing factors.

Data collection will occur in the following four locations with varying levels of campaign activity:

1. an area that has had an intense, long-running active campaign, of which the Island of **Puerto Rico** is the only such location
2. a current intense active campaign that has been taking place in the **Miami DMA** (designated market area)
3. a newer campaign area with mass media plus digital of which the **Houston DMA** is typified as representing, and,

4. a control area that currently has had no significant campaign efforts implemented and of which the state of **Mississippi** would represent.

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 three additional domestic US locations; 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 likelihood 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

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.

The purpose of this data collection is to conduct the third and final wave of an evaluation survey to assess CDC's communication and education effort to prepare and protect populations at risk of contracting the Zika virus in the domestic U.S and Puerto Rico. This data collection request includes a single, cross-sectional survey to assess current attitudes, beliefs and behaviors related to CDC's Zika Domestic Readiness campaign.

The Zika Readiness Initiative campaign has been implemented in two phases with peak campaign activity coinciding with the height of mosquito season during the summer months of 2016 (phase 1) and 2017 (phase 2). ICR emergency approval was granted in 2016 to conduct the first two waves of data collection which captured the effectiveness of the first phase of the campaign. The third wave of data collection will allow CDC to capture the effectiveness of the second phase of the campaign being implemented through late summer/early fall 2017. While the campaign objectives and the call to action remain the same across both phases, campaign materials have been modified based on the findings from the first phase to better address misinformation about Zika and promote a greater sense of urgency to adopt preventive actions.

As the second phase of the campaign is launched in the summer of 2017 with revised campaign materials, a third survey wave will be conducted utilizing identical methods as the first two waves to allow CDC to assess the effects of the revised campaign materials. This information is vital to CDC's continued understanding of how the campaign served its purpose to prepare and protect populations at risk of contracting the Zika virus in the domestic U.S and Puerto Rico.

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 Puerto Rico and several US states, 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. Process evaluation data will be used to enhance and revise existing materials and future implementation plans. Additionally, these data may offer lessons learned to inform future communications on infectious disease outbreaks and may be shared with others in the field through publications and presentations.

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.

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

This is not a duplicative effort. 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 communication and education initiative launched by CDC, no other agency is anticipated to be collecting similar data specific to this campaign. The proposed assessment will allow CDC to significantly improve its ability to develop, refine and monitor communication and education activities as the

initiative evolves. Based on the data collected during the first two survey waves, campaign materials were revised to better address misinformation about Zika transmission and promote a greater sense of urgency to adopt protective behaviors. The third wave of the survey, to be conducted following the launch of the second phase of the campaign using revised campaign materials, will provide new information on whether campaign objectives were met as intended during the second phase. 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 to assess knowledge, attitudes, and behaviors of Zika virus prevention 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 evaluated, 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. The 60-day Federal Register Notice was published in the Federal Register on March 27, 2017, Vol. 82, No. 57, pp. 15222–15232(See Attachment B). CDC did not receive public comments related to this notice. A 60-day Federal Register Notice is included as Attachment B.

Additionally a 30-day Federal Register Notice will be published following the 60-day notice to inform the public of comments received and is included as Attachment C.

B. Communication partners, both domestically in the US and in Puerto Rico, have provided feedback 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 all information provided 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.

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

11. Justification for Sensitive Questions

Participants will be asked questions pertaining to safe sexual behavior, such as if they are consistently and correctly using 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 14 minutes per survey. The survey will be conducted using random digit dialing. In the domestic U.S., the questionnaire (Attachment E – Zika Readiness Initiative Survey (English); Attachment F – Zika Readiness Initiative Survey (Spanish)) will be administered to 1800 participants 12-months post-launch of the initiative to assess longer term outcomes. As shown in Table 12.A, 600 surveys will be administered in Puerto Rico, for a total of 2400 surveys. It is estimated that the total burden across both respondent types will be 560 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	1800	1	14/60	420
Puerto Rico Adults	Zika Readiness Initiative Survey	600	1	14/60	140
TOTAL		2400			560

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 $13,009.

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	420	$23.23	$9,757
Puerto Rico Adults	Zika Readiness Initiative Survey	140	$23.23	$3,252
TOTAL	**--**	**480**	**$23.23**	**$13,009**

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 third wave of the survey will span 6 months, beginning in March 2017 and ending in September 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 $36,461. This includes the cost of initiating the random digit dialing program, conducting the interviews, and analyzing the interview responses ($22,461) plus 20% of a GS-14 CDC employee's time over a six month period at $140,000 annual salary ($14,000).

Table 14: Estimated Annualized Cost to the Federal Government

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

15. Explanation for Program Changes or Adjustments

There are no program changes and adjustments 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. A final report will be prepared following the completion of data collection. The final report will present data from all three survey waves and will allow for assessment of long-term (12-month) changes in knowledge, attitudes and behavioral intention to adopt

recommended behaviors to protect against Zika virus. Additionally, manuscripts will be submitted to peer-reviewed journals, along with abstracts for conference presentations.

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
Third wave of random digit dialing interviews in the domestic US and Puerto Rico	1 week after OMB approval
Complete data analysis	5 weeks after OMB approval
Final report and recommendations to CDC	2 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.

(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, Diciembre 8). Informe Semanal de Enfermedades Arbovirales- Semana 47 (18 al 24 de Noviembre de 2016).

(5) *Case Counts in the US* (2016, December 14). Retrieved August 15, 2016, from CDC: https://www.cdc.gov/zika/geo/united-states.html

ATTACHMENTS

Note: Attachments are included as separate files as instructed.

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

Attachment B – FRN 60 Day Notice

Attachment C- FRN 30 Day Notice

Attachment D - IRB Determination Letter of Exemption

Attachment E - Zika Readiness Initiative Survey – English

Attachment F – Zika Readiness Initiative Survey - Spanish