

**Zika Emergency Package V:
Assessment of Interventions Intended to Protect Pregnant
Women in Puerto Rico from Zika virus Infections**

Request for OMB approval of an Emergency ICR

**Supporting Statement A
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- **Goals:** To assess the delivery and effects of interventions implemented in Puerto Rico to protect pregnant women from Zika virus infections and the birth defects that Zika virus can cause in their babies. As of April 26, 2016, interventions that have been implemented include:
 - Zika Education Sessions (at WIC clinics)
 - Zika Prevention Kits
 - Communications activities
 - Vector control services in and around the home of pregnant women [Indoor Residual Spraying (IRS), Outdoor Residual Spraying (ORS), and larviciding]
- **Intended use:** Information collected in this assessment will be used to help refine interventions that have been conducted to prevent and control Zika virus in Puerto Rico and to assess which interventions reduce risk and/or offer protection from Zika virus infections.
- **Methods:** Telephone interviews will be conducted with pregnant women in Puerto Rico. For assessment of intervention delivery and associated outcomes, a random sample stratified by pregnancy trimester will be drawn from WIC enrollment data. For assessment of risk and protective factors, a case-control approach will be used, drawing Zika-positive pregnant women in WIC and selecting matched controls from the same population (pregnant women enrolled in WIC).
- **Subpopulation:** Pregnant women living in Puerto Rico enrolled in the federal supplemental nutrition program for Women, Infants, and Children (WIC).
- **Data analysis:** Quantitative data will be analyzed using SPSS or SAS. Qualitative data will be transcribed. The text responses will be uploaded to NVivo, ATLAS ti, or MAXQDA and analyzed for themes.

This is an emergency request for a new information collection for six months. This ICR includes two projects, which are part of CDC's ongoing response in Puerto Rico to the Zika virus outbreak. Information collection is not expected to exceed six months. If it does, however, a formal ICR will be submitted to OMB in order to continue information collection.

1. Circumstances Making the Collection of Information Necessary

In December 2015, the Commonwealth of Puerto Rico, a United States territory, reported its first confirmed locally transmitted Zika virus case.

Starting in March 2016, The Centers for Disease Control and Prevention's (CDC) National Center for Emerging and Zoonotic Infections Diseases (NCEZID) initiated several interventions targeting pregnant women. The ultimate goal of these interventions is/was to protect pregnant women from Zika virus and encourage Zika prevention behaviors among pregnant women. The interventions include the following:

1. Zika Education Sessions (at WIC clinics)
2. Zika Prevention Kits;
3. Communication activities, and
4. Vector control services in and around the home of pregnant women (Indoor Residual Spraying, Outdoor Residual Spraying, and larviciding).

The Zika Prevention Kit is a tote bag that contains: insect repellent, educational materials about Zika prevention, condoms, a thermometer, mosquito dunks for treating accumulated water, and a bed net. The objectives of the Zika prevention kit were to increase women's knowledge of Zika prevention behaviors and provide women with the tools needed to engage in Zika prevention behaviors (e.g., insect repellent, condoms, and a bed net). In March 2016, an assessment of the Zika Prevention kit among pregnant women in Puerto Rico was conducted (OMB Gen IC No. 0920-1071).

In the coming weeks, a mass media communication campaign and community engagement/outreach efforts focused on reducing mosquito breeding sites will be added as important interventions that will involve non-pregnant audiences for action but with the motivation of protecting pregnant women and their babies (OMB Gen-IC No. 0920-0572).

In March 2016, an assessment was conducted among pregnant Puerto Rican women about their personal protective behaviors for Zika prevention as well as their perceptions of vector control strategies (OMB Gen IC No. 0920-0572). Both this assessment and the one done for the Zika prevention kits gathered qualitative insights from pregnant women that were helpful in describing the perceptions of pregnant women about many Zika prevention activities.

In June 2016, WIC and PRDH labs successfully merged information about interventions received by WIC enrollees and information about Zika laboratory testing results. In a presentation given to CDC's Director, Dr. Thomas Frieden, on June 11th, it was noted that, of the 575 women who received a Zika Prevention Kit that were reported to PRDH either as a suspected Zika virus disease case or for screening of asymptomatic pregnancy, 20 reportedly have tested positive for Zika virus infection. Dr. Frieden suggested that CDC and PRDH perform a case-control analysis to determine if there were factors, especially behavioral factors, associated with the Zika Prevention Kits or not, that were associated with the Zika virus infection in these 20 women.

This request is for data collection over the next six months related to Zika prevention efforts that have been and will be implemented in Puerto Rico to provide information on intervention delivery and associated outcomes as well as for completion of a case-control analysis. Specifically, CDC needs this assessment to ensure that Zika prevention activities effectively educate, equip, and encourage women to participate in as many Zika prevention behaviors as possible. On-going assessment is an important part of this program because it can reveal novel ways that women protect themselves from Zika, how effective the distribution of the Zika

Prevention Kit has been in Puerto Rico, perceived severity and susceptibility to Zika, pregnant women's self-efficacy in protecting themselves from Zika after the interventions have been implemented, as well as the extent to which target populations are using contents of the Zika Prevention Kit.

Interviews with pregnant women in Puerto Rico can help articulate motivations for and against engaging in Zika prevention behaviors that are critical for preventing Zika-associated birth defects and morbidities. Implementing changes based on results from this assessment is expected to facilitate program improvement and ensure the most efficient allocation of resources for this public health emergency. Understanding risk and protective factors related to interventions and behaviors of pregnant women can help to establish priorities.

2. Purpose and Use of the Information Collection

The goal of the first project is to find out if interventions are reaching pregnant women and having the intended outcomes along with getting feedback from pregnant women about the Zika prevention activities that have been implemented (e.g., Zika education sessions and prevention kits, vector control services, and communication activities). Attachment H shows a logic model of the interventions and their intended outcomes. Because there are many types of interventions targeting pregnant women as well as efforts to engage community members to take action on behalf of pregnant women, the team has proposed two telephone surveys to assess exposure to receipt of interventions as well as the intended outcomes of the interventions. Most of the questions in the initial telephone interview measure the interventions (left side of model) along with important factors while the second interview focuses mostly on the intended outcomes of the interventions (right side of logic model). Follow-up telephone calls will be initiated two weeks after the initial telephone interview. This provides enough time for initial responses and topics covered in the initial survey to be firmly removed from short-term memory.

While it is possible for the assessment to try to assess all of these factors in one telephone interview, it would be a very long telephone interview which pregnant women might be less likely to participate. In addition, there are several reasons why the team proposed an approach of conducting an initial interview followed by another brief telephone interview:

- The interventions and behavioral recommendations that are targeting pregnant women are numerous and complex. The main focus of the first interview is to assess exposure or receipt of messages and/or interventions that are targeting them as well as some preliminary feedback on relevance (beliefs about personal risk), resources (physical and social supports), initial responses or actions they are taking and beliefs about what they need or think is needed to protect pregnant women and their babies. The second interview does not ask about interventions aimed to help them, but rather gathers self-reported information on the key behavioral recommendations for pregnant women along with their report of any community action/mobilization regarding Zika virus prevention.

- A telephone interview offers an opportunity to remind and/or clarify to pregnant women what the important protective behaviors are as well as to hear obstacles they may be encountering and to make connections to services or resources that can help them overcome obstacles. WIC and PRDH are keenly interested in responding to insights gathered each month to improve the supports that are being offered to pregnant women.
- Zika outbreak response and prevention efforts are dynamic and evolving and are almost as dynamic as the pregnancy experience itself. The behaviors we are asking pregnant women to engage in need to be performed from conception to delivery – and establishing and maintaining those behaviors requires many different types supports – which is why many of the interventions have been designed and are being delivered. As the epidemic evolves, we will need to evolve based on new information about Zika but also new information about the needs of the pregnant women we are speaking with. A second call gives the pregnant woman a second opportunity to share her experience in performing behaviors and in witnessing community action (or inaction) in the context of change.

We believe that the approach of interviewing a pregnant woman in two brief telephone surveys will offer intended beneficiaries of interventions to provide important feedback on the services so that program deliverers can make improvements in real-time. Because each respondent will only receive 1 initial interview followed by 1 follow-up interview, the information collection will not be burdensome to respondents.

Findings will be used to improve the delivery of interventions and to inform decisions about future Zika prevention activities for pregnant women in Puerto Rico. PRDH and CDC intends for these data to be collected in real time and used in real time. We expect to collect data on a monthly basis that is reviewed by incident management team members and used to improve interventions for pregnant women in Puerto Rico. The plan is to conduct up to 300 initial interviews and up to 150 follow-up interviews each month for six months. We aim to stay under the six month data collection timeframe for this project. All but the last follow-up survey will likely be completed. In order to stay within the six month timeframe, we will increase our telephone caller capacity to ensure that all follow-up calls are completed before the six month timeframe and we will stop making follow-up calls at the six month mark and use whatever number of completed interviews we have at that time. Since we hope to start this work soon, the six month mark will likely fall in late December, a time when the availability of telephone callers and pregnant women may be much less than at other times of the year. The team will have a better idea of how to address possible challenges after we have a few months of experience with conducting the initial and follow-up interviews. Each month, information collected will be analyzed and a report developed and delivered to the leaders of the response. We expect that the reports will offer insights on the delivery of interventions to pregnant women. The information will be used to make recommendations for improving interventions. Information may also be used to develop presentations, reports, and manuscripts to document the program and lessons learned in order to inform future programs of this sort.

The goal of the second project is to get a better understanding of what the risk and protective factors are between pregnant women who have tested positive for Zika and comparable pregnant women who have not tested positive for Zika.

All results for Zika virus testing in Puerto Rico are currently captured in the Dengue Laboratory Samples Database (DLSDB) system. WIC ZPK distribution records and orientation information are captured in a separate database housed at PRDH. Case information from these databases will be merged to identify women who received ZPKs and were also reported to PRDH for Zika virus diagnostic testing. Women who tested positive for Zika virus infection (cases) will be matched with three women with negative Zika test results (controls). We expect to identify no more than 50 cases and 150 controls for this assessment.

Cases and controls will be contacted by telephone and interviewed using questions from Attachment E about demographic and household characteristics, behaviors, and Zika Prevention Kit use including Zika knowledge, use of insect repellent, larvicide, condoms, bednets, and indoor or outdoor residual spraying. Results will be compared between groups to identify factors associated with protection from Zika virus infection. Data will be entered into a secure EpiInfo7 database, and analyzed with SAS statistical software. Odds ratios between cases and controls will be analyzed to identify statistical differences between groups.

The purpose of both of these assessments is to assess core components of CDC's Zika response in communicating prevention behaviors, risk messages to the public about vector control services, and the Zika Prevention kit.

The following factors will be assessed:

- Exposure/experience with receiving interventions targeting pregnant women
- Knowledge about Zika virus and related prevention behaviors
- Self-efficacy in engaging in Zika prevention behaviors
- Engagement in Zika prevention behaviors (e.g, protective clothing use, condom use, and bed net use)
- Knowledge about, attitudes about, and use of the Zika Prevention Kit materials
- Knowledge about, attitudes about, and use of environmental vector control activities
- Risk perceptions of Zika
- Exposures to communications along with other factors that may be important considerations in their taking action or not (e.g., does their house have screens, etc.).

For the first project, we will conduct telephone interviews with a mix of closed-ended and open-ended questions with pregnant women. We estimate 1,800 pregnant women will participate in the project over a six month period. For the second project, we will complete 200 interviews

with a mix of closed-ended and open-ended questions. We estimate that interviews will be completed within three months.

Results of this project will have limited generalizability. However, results of this assessment should provide information that can be used to enhance and revise the existing program as well as offer lessons learned to inform infectious disease control programs that use education materials.

3. Use of Improved Information Technology and Burden Reduction

For each project, collected data will be entered into a computer that is preloaded with an Epi-Info form that will be developed specifically for this effort. However, paper documents will be available as a backup due to intermittent electricity and technology access. Telephone interviewers will be responsible for data entry and the project manager will perform data quality control measures.

4. Efforts to Identify Duplication and Use of Similar Information

As such, CDC is not aware of any other systematic collection of the information described herein.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

CDC has contracted with Caduceus to provide support services for Zika related efforts. According to its website (www.caduceusstaffing.com), Caduceus is a "Certified and Verified 8(a), HUBZone, and Service Disabled Veteran Owned Small Business (SDVOSB) that provides healthcare, information technology and security, and scientific services for our clients." Caduceus staff will place the phone calls and enter data from the phone calls for this project.

6. Consequences of Collecting the Information Less Frequently

For the first project, this request is for a one time data collection that involves two encounters (an initial interview and a follow-up interview) related to newly established Zika prevention outreach efforts that are a result of an unprecedented public health emergency. Specifically, without this information, CDC's ability to effectively serve pregnant women through education, communication, and services, may be compromised.

Assessment (feedback loop) is important to delivering multi-faceted interventions because it can reveal why specific activities occur—or do not occur—as planned, as well as showing whether the interventions are having the intended or unintended effects. In particular, results gained through this assessment can facilitate program improvement and ensure good stewardship of resources.

For the second project, this request is for a one time data collection that involves one telephone interview to assess behavioral factors associated with prevention of Zika virus infection. Findings from this assessment will be used to guide current prevention efforts and provide feedback about intervention effectiveness and outcomes.

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

The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

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

A. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived.

B. Leaders in the Puerto Rico Department of Health’s incident command structure have been involved in discussions and decisions about this assessment. Puerto Rico leaders recommend that all telephone interviewers be locally employed staff who speak Spanish.

C. CDC’s Director, Dr. Tom Frieden, has requested that the case –control approach be done since data linkages between WIC and PRDH labs make this approach possible.

9. Explanation of Any Payment or Gift to Respondents.

CDC and contractors will not provide payments or gifts to respondents.

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

NCEZID’s Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. No information in identifiable form will be collected.

Impact the proposed collection will have on the respondent’s privacy

For project 1: Prior to participating in the assessment via telephone, the telephone interviewer will read prospective respondents their rights as participants, and contacts for more information about the project. Verbal consent from the participant will be requested. Prior to the beginning of

the assessment, a staff member will also address any questions the participants have about the project. Participants must provide verbal consent at the time of each interview before any information will be collected.

The assessment has no foreseeable risks other than the very low risk of breach of security. Women are not required to participate. The choice to participate is completely voluntary and will not have any influence on their WIC eligibility status. Participants have the right to withdraw at any time for any reason. None of the information being collected would reasonably place subjects at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputations. The data collected will be retained for up to one year and then all data will be destroyed.

For project 2: Prior to participating in the assessment via telephone, the telephone interviewer will read prospective respondents their rights as participants, and contacts for more information about the project. Verbal consent from the participant will be requested. Prior to the beginning of the assessment, a staff member will also address any questions the participants have about the project. Participants must provide verbal consent at the time of each interview before any information will be collected.

This assessment would access already collected medical data about participants; new information to be collected would not gather sensitive questions about participant's health status or outcomes of infection. None of the information being collected would reasonably place subjects at risk of criminal or civil liability. All personally identifiable data will be captured and stored in the current secure database for Zika laboratory results. All interviewers will be trained in protection of personally identifiable information and data security; however, only project management personnel will have access to the Zika laboratory database, and interviewers will be given the minimal amount of identifiable data needed to contact eligible persons. The project database, including participant responses, will not contain personal identifiers and will be stored in a secure EpiINFO database. Women are not required to participate; the choice to participate is completely voluntary and will not have any influence on their WIC eligibility status. Participants have the right to withdraw at any time for any reason. The data collected will be retained for up to one year and then all data will be destroyed.

Final reports, manuscripts, and presentations will contain no information regarding identities of the participants. All collected data will be destroyed within one year after the data collection is complete.

Whether individuals are informed that providing the information is voluntary or mandatory

For both projects, participation in the assessment is voluntary. Prior to the beginning of the information collection, a staff member will also address any questions the participants have about the project and provide a CDC project email and phone number. Participants must provide verbal consent at the time of each telephone interview before any information will be collected.

Telephone interviews will only be conducted with those who agree to participate. Participants will be informed they are free to skip questions they do not wish to answer, respond “I don’t know,” or end the interview at any time for any reason. Once informed of this information, participant’s agreement to participate in the interview will be their consent to participate in the assessment.

Opportunities to consent, and share submission of information

For both projects, participation in the assessment is voluntary. Participants must provide verbal consent at the time of the telephone interview before any information will be collected.

Telephone interviews with pregnant women will only be conducted with those who agree to participate. Participants will have to provide consent before the initial interview and the follow-up interview.

Information secured

Stringent safeguards are in place to ensure a respondent’s security including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC’s and the contractor’s computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of CDC staff or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at the Emergency Operations Center in Puerto Rico.

Procedural safeguards: Protections for computerized records include programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic medical containing Privacy Act information. Finally, CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room,

admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts and the CDC Project Director, contract officers and project officers oversees compliance with these requirements.

System of Records

No system of records is being created for this information collection.

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

Sensitive questions

For project 1: No sensitive questions will be asked during the initial telephone interview (Attachment C). However, questions about behaviors related to the sexual transmission of Zika virus will be asked in the follow-up telephone interview (Attachment D). For example, participants will be asked about intercourse and condom use behaviors. To minimize the possibility of distress, participants will be informed that the interview is voluntary, and they are free to skip questions they do not wish to answer, respond “I don’t know,” or end the interview at any time for any reason.

For project 2: Questions about behaviors related to the sexual transmission of Zika virus will be asked (Attachment E). For example, participants will be asked about intercourse and condom use behaviors. To minimize the possibility of distress, participants will be informed that the interview is voluntary, and they are free to skip questions they do not wish to answer, respond “I don’t know,” or end the interview at any time for any reason.

IRB Approval

Both projects were reviewed by the Scientific Regulations Advisor for the National Center for Emerging and Zoonotic Infectious Diseases and determined to be “public health non-research” (Attachments F and G).

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on the experience of the team lead in developing comparable telephone interview scripts for a similar assessment project involving telephone surveys with Hispanic women of childbearing age (Flores, Prue, & Daniel, 2007). For project 1, the Initial Telephone Interview (Attachment C), including time for reviewing instructions, will take approximately 20 minutes, and the follow-up interview (Attachment D) is expected to last 15 minutes. For project 2, the Telephone Interview for Cases and Controls (Attachment E) will take approximately 20 minutes.

Table A: Estimated Annualized Burden Hours and Costs

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Burden Hours
Project 1					
Pregnant WIC participant	Initial Telephone Interview	1,800	1	20/60	600
	Follow-up Telephone Interview	900	1	15/60	225
Project 2					
Pregnant WIC participant	Telephone interview of cases and controls	200	1	20/60	67
					892

Respondents will be drawn from enrollees of Puerto Rico’s supplemental food and nutrition assistance program called Women, Infants, and Children’s (WIC). The program bases eligibility on household income. According to a report by the USDA’s Food and Nutrition Service examining nutrition assistance benefits in Puerto Rico (<http://www.fns.usda.gov/sites/default/files/ops/PuertoRico-Cash.pdf>), most beneficiaries came from households with 4 or fewer people. Since unemployment is high in Puerto Rico and incomes have been decreasing and are much lower than mainland mean hourly wages, we weighted the annual household income eligibility requirements for WIC by the proportion of households in each category. The following table shows the household size, income eligibility, proportion of program participants.

Household size	Annual income eligibility level	Proportion of Nutrition Assistance Program Participants in Puerto Rico
1	\$21,775	24.9%
2	\$29,471	31.5%
3	\$37,167	19.8%
4	\$44,863	2.9%

$$[.249 \times \$21,775 + .315 \times \$29,471 + .198 \times \$37,167 + .029\% \times \$44,863] = \$23,365.75 \div 52 \text{ weeks} \div 40 \text{ hours} = \$11.23$$

Based on the calculated hourly wage rate of \$11.23, Table 12 shows the estimated burden and costs for 1,800 respondents using the Initial Telephone Interview Guide (Appendix C), and 900 respondents using the Follow-up Telephone Interview Guide (Appendix D).

Table B. Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pregnant WIC participant	Initial Telephone Interview	600	\$11.23	\$6,738.00
	Follow-up Telephone Interview	225	\$11.23	\$2,526.75
	Telephone interview of cases and controls	67	\$11.23	\$752.41
892				\$10,017.16

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

There will be no costs to the participants other than their time to participate in the telephone interviews.

14. Annualized Cost to the Government

There are no equipment costs. The only cost to the federal government would be the travel and salary of the CDC staff supporting the design (protocol and instrument development as well as IRB and OMB approvals), implementation (data collection), and analysis and reporting. The estimated cost to the federal government rates were obtained from the Office of Personnel Management’s website (<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2014/general-schedule/>) using Atlanta, Georgia localities. Actual salaries may vary by the location and step for each participating employee. The total cost is \$60,828.90. Table 14 describes how this cost estimate was calculated.

Table C: Annualized Cost to the Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Operations Director of Puerto Rico Zika Response (Commission Corps, Medical Officer)	30	\$74.70	2,241.00
Associate Director for Behavioral Science, NCEZID (GS 15) Primary in assessment design, data analysis, and outputs.	60	\$ 76.46	\$4,587.60

Supervisory Epidemiologist, Dengue Branch, (Commissioned Corps, Scientist Officer)	30	\$ 55.50	\$1,665.00
Epidemiologist, NCEZID's Dengue Branch (Commissioned Corps, Veterinary Medical Officer)	120	\$ 42.31	\$5,077.20
Behavioral Scientist, CDC deployee to Puerto Rico Health Department (GS 13) Primary in oversight data analysis, and outputs. Support in data collection	120	\$ 42.31	\$5,077.20
Health scientist/Evaluation fellow NCEZID (GS 12) Support for data analysis and reporting.	180	35.58	\$6,404.40
Public health educators/communication specialists, and analysis (Caduceus contractors hired locally in Puerto Rico)(Contractor) Primary in data collection - conducting telephone interviews	2074	\$ 17.25	\$35,776.50
Estimated Total Cost of Information Collection			\$60,828.90

Contractor pay based on Bureau of Labor statistics wage estimates for “Telephone operators.”
Operations Director of Puerto Rico Zika Response (Commission Corps, Medical Officer) pay
based on 05 level.

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

A summary of this timeline is provided below:

Project Time Schedule	Timing
OMB approval	By June 24
Data Collection	For project 1: June 27-December 27 For project 2: June 27 – September 27
Data Analysis	For project 1: Data analysis will begin the week data collection occurs, and continue throughout the data collection process on a monthly basis

	For project 2: Data analysis will begin the week data collection occurs and continue on an on-going basis until data collection is complete.
Monthly report and communications for making improvements to interventions	For project 1: 2 weeks after prior months data collection For project 2: A preliminary summary report will be available within 2 weeks after half the sample size is collected (25 cases and 75 matched controls). Final report will be available within 2 weeks after whole sample is collected (50 cases and 150 controls).
Improvement of intervention efforts	For project 1: 2 weeks after monthly report For project 2: 2 weeks after data collection is completed.

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

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

- A. Authorizing Legislation – Public Health Service Act
- B. 60-Day FRN
- C. Initial Telephone Interview of Women
- D. Follow up Telephone Interview of Women
- E. Telephone Interview of Cases and Controls
- F. IRB Letter of Determination for Project 1
- G. IRB Letter of Determination for Project 2
- H. Logic Model of Puerto Rico Zika Response Activities

References

Flores AL, **Prue CE**, Daniel KL (2007). Broadcasting Behavior Change: A comparison of the effectiveness of paid and unpaid media to increase folic acid awareness, knowledge, and consumption among Hispanic women of childbearing age. *Health Promotion Practice*, 8 (2), 145-153.

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<http://www.fns.usda.gov/sites/default/files/ops/PuertoRico-Cash.pdf>