

## **Supporting Statement A**

### **Emergency Zika Package: Zika Postpartum Emergency Response Survey, Puerto Rico, 2016**

Request for OMB approval of an Emergency ICR

OMB number xxxx-xxxx

**New**

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- **Goal of the study:** To conduct a rapid, population-based assessment of maternal behaviors and experiences related to Zika virus exposure among recently pregnant women in Puerto Rico.
- **Intended use of the resulting data:** To inform decisions by the CDC and Puerto Rican health authorities related to immediate refining of messaging, communications, and education materials for pregnant women and their health care providers in Puerto Rico.
- **Methods:** Puerto Rico Zika Postpartum Emergency Response (ZPER) will employ hospital-based data collection. The operational target population is all women delivering a birth in selected Puerto Rican hospitals during the surveillance period.
- **The subpopulation to be studied:** The population of interest for ZPER is all women who delivered an infant at a maternity hospital with 100 or more births per year in Puerto Rico during the surveillance period.
- **How data will be analyzed:** Data collection will be done on paper forms and/or tablets. Data entry for both paper forms and tablets will be programmed using SPSS survey software. SAS, SPSS, SUDAAN or STATA will be used for data analysis.

## 1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification “New” request. The length of data collection request for Office of Management and Budget (OMB) approval is six (6) months. If more than six months are needed to complete this information collection, CDC will pursue a formal ICR. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at the Centers for Disease Control and Prevention (CDC) is making this request as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment A**).

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. The Puerto Rico Department of Health became the first U.S. jurisdiction to report autochthonous transmission of Zika virus in December 2015. Puerto Rico has reported the highest number of Zika Virus cases in the U.S. and the number is expected to rise. From November 1, 2015 to June 17, 2016, there were 1726 laboratory-confirmed cases of Zika virus infection in Puerto Rico. Of those, 191 were pregnant women.

While pregnant women do not differ from the general population in terms of susceptibility to Zika virus infection or severity of disease, they are at risk for adverse pregnancy and birth outcomes associated with Zika virus infection during pregnancy including pregnancy loss, congenital microcephaly, other brain malformations, ocular birth defects, severe arthrogryposis in the legs and arms, club foot and

shortened neck. After review of the available evidence, CDC recently concluded that Zika virus infection during pregnancy is a cause of microcephaly and other brain defects<sup>1</sup>.

Currently no vaccine or medication exists to prevent or treat Zika virus infection. CDC issued interim guidelines for health care providers caring for pregnant women and women of reproductive age with possible Zika virus exposure, as well as guidelines for the evaluation and testing of infants with possible congenital Zika virus infection. This guidance includes screening and testing recommendations for symptomatic and asymptomatic pregnant women<sup>2</sup>; recommendations for contraception counseling, family planning, preconception health counseling<sup>3</sup>; and screening and testing of infants born to mothers who traveled to or resided in areas of Zika virus transmission<sup>4</sup>. As more recent data have emerged, CDC has also issued interim guidance on the prevention of sexual transmission of the Zika virus by men to pregnant and non-pregnant partners<sup>5</sup>.

A rapid assessment of maternal-related behaviors and experiences in regard to Zika virus in Puerto Rico will provide information on prenatal experiences such as discussions with providers, testing for Zika and sources of information, as well as behaviors employed to reduce sexual and vector-based exposure to the Zika virus. By surveying women starting in August 2016, the study will be capturing women who conceived approximately in November (based on delivery of term infants), and whose pregnancies coincided in their entirety with the outbreak, to date. By continuing the study over 3 months, the survey will capture changes in awareness and behaviors of providers and pregnant women between the early period of the outbreak, and later in the outbreak when understanding and messaging around the prevention activities evolved. In addition to prenatal information, the survey will collect information on contraceptive use immediately postpartum, a key strategy to reduce Zika-affected pregnancies. Given that endemic presence of the vector in Puerto Rico, it is not expected that transmission will end or be significantly reduced within the 3-month timeframe of this study in the absence of a vaccine or prophylactic treatment. As such, the survey will be capturing information on behaviors and experiences during pregnancies that occurred during the entire first year of the outbreak, and the information will be available “real-time,” for women who just delivered their infants.

The Zika Postpartum Emergency Response Survey is designed to capture women of any age who have recently had a live birth. In addition, the strategies to increase use of highly effective contraception in the immediate postpartum period are more targeted and specific than those employed in the general population of women of reproductive age. For example, provision of immediate postpartum long acting reversible contraception (LARC) reduces barriers that include returning for postpartum visit for contraception care or discontinuation of public insurance coverage<sup>7</sup>.

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

The objective of this assessment is to conduct a rapid, population-based assessment of maternal behaviors and experiences related to Zika virus exposure among recently pregnant women in Puerto Rico who delivered a baby in a hospital in Puerto Rico with 100 or more births per year. This information will provide the Puerto Rican government and CDC’s emergency response team.

The data collected by the Zika Postpartum Emergency Response Survey is designed to specifically inform decisions related to immediate refining of messaging, communications, and education materials for pregnant women in Puerto Rico. It will be used to inform guidelines for prenatal care providers

related to counseling of pregnant patients and testing for Zika virus, and will provide data on the prevalence of first and second trimester Zika testing. It will also be used immediately to assess adoption of preventive behaviors that can minimize the risk of vector-borne and sexual transmission of Zika virus among pregnant women. A chief objective of this collection that distinguishes this survey from other related surveys (see Section A.3) is the assessment of in-hospital provision of long-acting reversible contraceptives (LARCs) to women who have just given birth, which could be highly effective in preventing future Zika-affected pregnancies. Further, the sampling is designed to be able to provide regional estimates, therefore allowing for data to inform decisions both at the island-wide and at the local level.

The questionnaire (**Attachment B**) consists of several groups of questions on:

- Respondent demographics, knowledge and awareness of Zika virus transmission during pregnancy
- Prenatal care counseling and testing relate to Zika virus during pregnancy
- Practices to prevent vector-borne transmission during pregnancy
- Receipt of social services for vector control during pregnancy
- Practices to prevent sexual transmission of Zika virus during pregnancy, and contraception use prior to and after pregnancy

For example, information from Q9 & Q14-Q19 will provide data on trusted sources for receiving information about Zika virus and uptake of preventive strategies by women during pregnancy (data will be generalizable to pregnant women territory wide, as well as regionally) for protection from mosquito-related transmission of Zika. Gaps identified in uptake of preventive behaviors will inform risk reduction messaging to the pregnant women and to health care and social service providers. Q10-Q13 will provide data on receipt of health care provider recommendations that will also inform educational materials, messaging and guidelines developed for clinical providers of service to pregnant women. Q20-22 provide information on proportion of pregnant women who have recently received WIC services, receipt of prevention services and kits received by WIC services (of note, the OMB PRA collection 0920-1118, **Zika Emergency Package V: Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections** is specific to pregnant women who have received WIC services only). Q24-34 provide data on behaviors related to prevention of sexual transmission of Zika virus. In addition, information on pregnancy intent and pre-pregnancy contraceptive use Q35-Q37 will inform ongoing messaging and counseling around women who may have wanted to avoid or delay pregnancy. Q38 provides data on postpartum contraceptive use, prevention of rapid repeat pregnancies are important strategy for reduction of adverse outcomes related to Zika infection during pregnancy.

The Zika outbreak has been ongoing in Puerto Rico since November 2015. By surveying women starting in August 2016, the study will be capturing women who conceived approximately in November (based on delivery of term infants), and whose pregnancies coincided in their entirety with the outbreak, to date. By continuing the study over 3 months, the survey will capture changes in self-reported awareness and behaviors of providers and pregnant women between the early period of the outbreak, and somewhat later as the understanding and messaging around the prevention activities has increased and evolved. Given that endemic presence of the vector in Puerto Rico, in the absence of a vaccine or prophylactic treatment, it is not expected that Zika transmission will be

completely significantly reduced or eliminated within the 3-month timeframe of this study. This survey will be capturing information on behaviors and experiences during pregnancies that occurred during the entire first year of the outbreak, and the information will be available “real-time,” for women who just delivered their infants. Survey responses will be uploaded at the end of each day to the CDC server allowing for up-to-date calculations of survey estimates. This information will be available to Puerto Rico and CDC staff.

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

One-hundred percent of burden hours will be incurred by respondents during interview completion at the time of their delivery stay in the hospital. The minimum amount of questions needed to assess maternal behaviors and experiences related to Zika virus exposure are collected.

Data collection will be done on paper forms and/or tablets. Each field staff worker will have one tablet, so use of tablet versus paper will depend on the number of women a staff person has to interview on any given day, and the comfort level of the respondents. A respondent may request the paper form if they are not comfortable using the tablet. In the case of technical difficulties, the paper form will also be used. Data entry for both paper forms and tablets will be programmed into data collection system developed by CDC. The system uses the same base software (SPSS survey software) as the Pregnancy Risk Assessment Monitoring System (PRAMS) Integrated Data Collection System (PIDS) and other emergency response surveys conducted by CDC. The data collection system will be maintained by CDC and provided for use by the Puerto Rico Department of Health for this project.

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

The data collected by the Zika Postpartum Emergency Response Survey will compliment other Zika emergency response activities currently underway at CDC. First, this study will provide the only population-based source of data specifically restricted to women who have been recently pregnant, the priority population for interventions aimed at minimizing the Zika-affected pregnancies. It will allow for both island-wide and regional estimates to assess the reach of messaging about prevention activities, acceptance and adoption of prevention messages, receipt of health care and social service provider recommendations and services, and, importantly, assessment of the extensive contraceptive services expansion that is underway as part of the response effort. Further, it adds information where there may be gaps in other surveillance efforts that focus on all women or only a subset of pregnant women. For example, other surveys that have been approved as part of the Zika response only collect data on women who were WIC participants and received an interventions from the WIC program [0920-1118, **Zika Emergency Package V: Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections**. Data collected as part of, 0920-1114, **Emergency Zika Package IV: Assessment of Contraceptive Use and Needs, Puerto Rico, 2016** focuses on contraceptive use among women of reproductive age 18-49, however, given that only a small subset of the population is pregnant or postpartum in the population at any given time, contraceptive assessment for postpartum contraceptive use cannot be determined in this data collection.

The number of teen births (age < 20) is high in Puerto Rico<sup>6</sup>. The Zika Postpartum Emergency Response Survey is designed to capture women of any age who have recently had a live birth. In addition, the strategies to increase use of highly effective contraception in the immediate postpartum period are more targeted and specific than those employed in the general population of women of reproductive age. For example, provision of immediate postpartum long acting reversible contraception

(LARC) reduces barriers that include returning for postpartum visit for contraception care or discontinuation of public insurance coverage<sup>7</sup>. Formative evaluation of prevention messaging as it relates to Zika for pregnant women, community leaders and health care providers have been collected [Gen IC 0920-1050 **Formative Evaluation of Zika Prevention Kits for Pregnant Women in Puerto Rico**; Gen IC HMTS 0920-0572 **for Zika-related message development and testing**]; this data collection can inform ongoing refinement of these campaigns.

#### **4. 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.

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

This is a one-time information collection to assess various aspects of maternal behaviors and experiences related to Zika virus exposure among recently pregnant women in Puerto Rico.

Collecting information less frequently than the CDC recommendations would interfere with the public health actions required to contain and respond to Zika virus transmission and to do everything possible to limit, if not stop, adverse health outcomes and birth defects due to this disease.

#### **6. 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.

#### **7. 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. A 60-day Federal Register Notice was drafted (**Attachment C**).

B) There was consultation with the Puerto Rico Department of Health based on their prior experience conducting a maternal health survey of new mothers in the hospital after delivery.

#### **8. Explanation of Any Payment or Gift to Respondents**

There is no payment or gift to respondents.

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

The Privacy Act is applicable. Records are covered under CDC Privacy Act System of Records Notice (SORN) No. 0920-0136 "Epidemiologic Studies and Surveillance of Disease Problems" and SORN No. 09-20-0113, "Epidemic Investigation Case Records Systems Notice." All information collected shall be held in confidence to the extent allowed by law. All state staff and contractors involved in data collection shall be trained concerning procedures and practices to ensure privacy of data and shall sign a confidentiality pledge. Names will be collected for the purpose of locating and contacting participants in the hospital. No names will be collected with survey responses. A unique study ID will be assigned to each participant and used to track responses. Later probabilistic linkage of survey responses to information collected by the Puerto Rico Department of Health in their vital records system will allow for analysis of maternal and infant characteristics and outcomes collected by the birth certificate, but not the questionnaire such as birth defects. Completed questionnaires and any files with personal identifiers

must be kept in a locked file cabinet or a locked room; access to these files will be limited to ZPER project staff at the Puerto Rico Department of Health. All electronic files will have restricted access; the operations tracking software will be password-protected. Backup files of ZPER data will also be secured.

No additional personal identifying information will be included in the survey. The CDC will not include information in reports that may identify respondents. Information that could potentially be used to indirectly identify an individual will be suppressed; for example, aggregated data will not be stratified into subcategories that might allow for identification of individuals.

Prior to initiating the survey, each respondent will be provided with an informed consent documents **(Attachment D)**. This will be written and read by the respondents, but may also be read to the respondent by the field staff collecting the data. The consent will include information about the survey and the reason for its being conducted, including the potential for future data linkage. Potential respondents will be made aware that participation is purely voluntary. All respondent will sign the consent form if they agree to participate. There will be an additional assent form for any participants aged 14 years or younger.

ZPER is covered by an Assurance of Confidentiality **(Attachment E)**. The Assurance provides the confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

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

### *IRB Approval*

This protocol was submitted for Human Subjects Protection review on April 27, 2016 and approved on June 21, 2016.

### *Justification for Sensitive Questions*

Because many of the questions to be asked of respondents will deal with sensitive topics, including sexual activity, pregnancy, and contraception, all data collection staff will be female. Sensitive questions are essential to meeting the goals of this information collection. Steps to protect the privacy and confidentiality of information provided by respondents is included in Section A10.

## **11. Estimates of Annualized Burden Hours and Costs**

### *A. Estimated Annualized Burden Hours*



An invitation letter was sent to all 36 hospitals and they have each agreed to participate. Within each hospital, field workers will have direct access to existing hospital delivery logs to identify eligible women. No additional data will be collected from or by hospital staff therefore no additional burden will be placed on hospital staff. There will be approximately 432 sampling days across all 36 hospitals during the 3 month study period.

A total of 2,700 women who recently gave birth in a hospital with 100 or more births per year will be interviewed for this assessment.

Prior to beginning the survey, women will read and sign a consent form. This process should take 5 minutes. Those unwilling to participate will be thanked for their time and the interview will be terminated. Because there is no burden on these respondents as not data are collected, they are not included in the burden table below.

For those that do participate, it is expected that this questionnaire will take an average of about 15 minutes to complete. The total number of respondent burden hours is 920.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Women with recent births	Questionnaire <b>(Attachment B)</b>	2,760	1	20/60	920
<b>Total</b>					920

#### *B. Estimated Annualized Burden Costs*

There will be no anticipated costs to respondents other than time.

The average annual response burden cost is estimated to be \$21,371.60. The hourly wage estimates are based on the Bureau of Labor Statistics May 2015 National Occupational Employment and Wage Estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). The mean hourly wage rate for all occupations (\$23.23) was used.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Women with recent birth	Questionnaire <b>(Attachment B)</b>	920	\$23.23	\$21,371.60
<b>Total</b>				\$21,371.60

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

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

### **13. Annualized Cost to the Government**

The total estimated cost to the government is \$400,587. The table below includes the cooperative agreement funds provided to the Puerto Rico Department of Health to conduct ZPER and breaks down how many CDC employees will be working on this project, what percentage of their time will be devoted to this project, and how much they will make during this time. Information collection is expected to last no more than three months, though preparation and analysis will take seven months.

Hourly wages for CDC employees were based on Step 1 employees for the Atlanta locality available here: [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/ATL\\_h.pdf](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/ATL_h.pdf).

Grade	# of FTEs	Hourly Wage	% time devoted to project	Total Hours	Total
Cooperative agreement funds to Puerto Rico Department of Health	n/a	n/a	n/a	n/a	\$300,000
GS-14	1	\$50.00	25	280	\$14,000
GS-14	1	\$50.00	50	560	\$28,000
GS-14	1	\$50.00	20	224	\$11,200
GS-13	1	\$42.31	100	1120	\$47,387
<b>Total</b>					\$400,587

#### 14. Explanation for Program Changes or Adjustments

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

#### 15. Plans for Tabulation and Publication and Project Time Schedule

The CDC’s Division of Reproductive Health (DRH), in collaboration with the CDC Emergency Operations Center (EOC) will take responsibility for all data tabulations for this assessment. CDC’s Division of Reproductive Health (DRH), which coordinates all Pregnancy Risk Assessment Monitoring System (PRAMS) activities for the US, including Puerto Rico, will prepare the data files for analysis. This preparation will include final data cleaning and weighting. CDC epidemiologists and statisticians, including staff in DRH and EOC will develop an analysis plan and table shells during the data collection phase and will perform all data analysis on an ongoing interim basis and immediately upon availability of final data files. Interim preliminary reports, for internal use at the Puerto Rico Department of Health and CDC will be used to begin applying findings in Puerto Rico. Once final tabulations are available a final report will be published, as well as an MMWR article on key findings.

##### Project Time Schedule:

Preparations for data collection in Puerto Rico include: recruiting and hiring data collection staff, obtaining necessary space and computers, translation of questionnaire into Spanish, preparation of training materials, programming of questionnaire for data entry and editing, establishing contact with participating hospitals, and obtaining approvals.

- One week after approval: Training of interviewers
  - Who: Puerto Rico Dept. of Health
- Two weeks after approval: Development of interim and final data analysis plan
  - Who: CDC Division of Reproductive Health and CDC Emergency Operations Center

- Two weeks after approval: Piloting of data collection procedures and questionnaire
  - Who: Puerto Rico Dept. of Health and CDC Division of Reproductive Health
- Three weeks after approval: Begin interviewing 2,760 respondents (representative sample of women who are residents of Puerto Rico who gave birth in a hospital with more than 100 births per year); data collection will continue for 90 days after initiated
  - Who: Puerto Rico Dept. of Health
- Eight weeks after approval: Interim cleaning, weighting, and preparation of data for analysis begins; continues on an ongoing basis
  - Who: CDC Division of Reproductive Health
- Ten weeks after approval: Release of first set of preliminary estimates per analysis plan
- Fifteen weeks after approval: Release of second set of preliminary estimates per analysis plan
- Five months after approval: Final preparation of cumulated data for analysis
  - Who: CDC Division of Reproductive Health and CDC Emergency Operations Center
- Six to nine months after approval: Preparation of final assessment reports in Spanish and English
  - Who: CDC Division of Reproductive Health and Puerto Rico Department of Health

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

The OMB Expiration Date will be displayed.

#### **17. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

#### **References**

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2. Petersen EE, Staples JE, Meaney-Delman, D, et al. Interim Guidelines for Pregnant Women During a Zika Virus Outbreak — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2016;65:30–33. DOI: <http://dx.doi.org/10.15585/mmwr.mm6502e1>.
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**Attachments**

- A. Public Health Service Act (42 USC 241)
- B. Zika Postpartum Emergency Response Questionnaire
- C. Draft 60-Day FRN
- D. Informed Consent for Participants
- E. CDC Assurance of Confidentiality
- F. Sampling Size and Methods