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

Request for OMB approval of an Emergency ICR

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Supporting Statement B

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Table of Contents

1. Respondent Universe and Sampling Methods

The Puerto Rico Zika Postpartum Emergency Response (ZPER) will collect information from a representative sample of all women who are residents of Puerto Rico and delivered an infant in a hospital in Puerto Rico with 100 or more births per year. There is no age restriction, so any women with hospital birth during the data collection period will be eligible. According to 2015 birth data, 36 hospitals meet this eligibility criteria. These 36 hospitals accounted for 98.5% of all births in Puerto Rico in 2015. All 36 have agreed to participate in the survey. Data collection will take place over a 3-month period in 2016.

This survey will be self-administered by the respondent. Field staff from the health department will visit women in their hospital room 24-48 hours after the delivery and offer them the survey on a paper form or they may also complete on a tablet. Women who do not give birth in a hospital or in a hospital with more than 100 births per year will not be represented. There will be no additional follow-up for women who are discharged early from the hospital. In 2015, 98.5% of all Puerto Rico births occurred in a hospital with 100 or more births per year, so we do not expect these exclusions to significantly affect the survey results.

A hospital-based sampling frame will be identified by the hospital's delivery log. In most hospitals, the delivery log represents a complete and accurate account of all births occurring in the hospital. Mothers with a multiple gestation regardless of order will be included in sample if at least one infant is delivered in the sampling window. Mothers who are ill or suffering from complications of pregnancy and delivery will not be excluded, however contact with these women may be deferred until their condition improves prior to discharge.

For ZPER surveillance, there is particular interest from a public health perspective in making inferences by geographic region. A stratified random sampling plan is used so that inferences about prevalence rates for maternal behaviors and knowledge of Zika can be estimated with sufficient precision both overall in Puerto Rico, and within selected geographic regions. For ZPER, 8 geographic regions will serve as the sampling strata. The 8 regions are Arecibo, Aguadilla, Bayamon, Caguas, Fajardo, Mayaguez, Metro, and Ponce. The sampling will be further stratified by hospital, although proportional allocation will be used (each hospital within a region will have the same sampling fraction). A total of 2,760 women will be sampled during the study period. A detailed description of the Methods used to

determine overall sample size and sampling methods are described in **Attachment E** (Sampling Size and Methods)

Survey data will be weighted according to known distributions of region of residence, age group, and educational level to ensure that differences in response rates do not bias results. The primary limitation to the representativeness of the sample is the fact that a very small proportion of women in Puerto Rico do not give birth in a hospital. We anticipate that these limitation will minimally affect the representativeness of the estimates obtained.

2. Procedures for the Collection of Information

The hospital-based sampling frame is identified by the hospital's delivery log. In most hospitals, the delivery log represents a complete and accurate account of all births occurring in the hospital. Field staff from the Puerto Rico Department of Health will visit each hospital on the designated day, select the sample from the hospital birth log, and enter the information onto a data form. This is the manner in which study participants are recruited. Each sampled mother would be assigned a unique study ID that could later be used to link information from the birth log to information from the questionnaire. Health department staff will then visit each mother individually and offer her the opportunity to complete the interview on a paper form or using a tablet. For those responding on paper forms, these will be collected, tracked, and passed on for data entry and verification following the interviews each day.

There are several different methodologies that could be used to collect information regarding experiences and behaviors during pregnancy. Data collected from women who have recently had a baby is an ideal population to capture experiences around the time of pregnancy, as this group is easily identified from hospital logs, and pregnancies in this sample are not self-reported. Conducting a PRAMS-like survey using mail with telephone follow-up 2-4 months postpartum was considered, however given that the primary interest for ZPER is on experience during pregnancy, delaying the capture of information into the postpartum period was not necessary. Further, sampling in hospitals also eliminates the need to wait for processing of birth certificate records and eliminates the need to contact women after they leave the hospital. We felt that overall the best option for providing the information sought rapidly was to conduct a hospital-based survey.

The fact that the Puerto Rico Department of Health (PRDH) successfully conducting the Maternal and Infant Health Survey of Puerto Rico (ESMIPR) study in hospitals from 2002 to 2012 reinforced the decision to carry out a hospital-based survey. The PRDH leadership and staff have prior experience with this approach, and this strengthens the appeal.

Because some of the questions to be asked of respondents will deal with sensitive topics, including sexual activity, pregnancy, and contraception, all field staff workers will be female. Although the interviews will be self-administered, all field workers will also be Puerto Rican Spanish speakers.

Before data collection begins, the implementing organization will carry out several important tasks. Qualified interviewers will be recruited and hired. Additional space will be identified and rented to house the survey activity. Computers and other necessary equipment will be purchased. The questionnaire will be translated into Puerto Rican Spanish. The questionnaire must be put onto computers and the data entry program written.

3. Methods to Maximize Response Rates and Deal with No Response

Field staff workers will work closely with hospital staff to coordinate the best time to recruit women in their hospital rooms between 24-48 hours after delivery to ensure the best possibility of participation. Times of day can be varied, including weekends and during the evening, depending on each field workers assigned hospitals. Women will be offered either a paper form or a tablet, and can fill the survey out in the manner that is most comfortable for them. They do not need to respond verbally to an interviewer, as this may increase responses to sensitive questions. In addition, by recruiting participants and conducting the survey in hospital at time of delivery, we aim to decrease recall bias by collecting the information in the immediate postpartum period and decrease response bias by eliminating the need to contact women after they leave the hospital.

4. Tests of Procedures or Methods to be Undertaken

The implementing organization will spend one week training field staff workers on study procedures, on the use of the tablets, and use of the data entry system, including becoming familiar with the questionnaire content. This will include 1-3 days of pilot testing of the entire process in one selected hospital.

The Division of Reproductive Health (DRH) in the National Center for Chronic Disease Prevention and Health Promotion has agreed to perform several essential tasks for the project. First, they will take the lead in field testing of the elements of the questionnaire that have not been used previously in other surveys. This consists principally of questions directly dealing with Zika-related prevention behaviors and on the ways in which Zika virus has affected women's reproductive behaviors and intentions. DRH will also be responsible for developing and testing the data collection and data entry system that will be used on the tablets and for recording answers from any paper surveys. DRH will carry out all steps necessary following the completion of data collection to prepare the data files for analysis, including final cleaning, weighting, and readying the data for analysis.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Following preparation of the assessment's data files, data analysis will be carried out by staff from DRH, PRDH, and may also include staff detailed to CDC's Emergency Operations Center (EOC). While data collection is taking place, data analysis will be planned. Analytic staff from each participating group will collaborate to define a set of tabulations to be performed for the assessment and create table shells for the tabulations. It is expected that the principle tabulations will take about two weeks to perform, following completion of data processing and weighting. Those initial tabulations will provide information to answer all of the key questions the assessment is to address, described above. It is anticipated that tabulations will be done on a monthly basis after data collection is underway, as well as published in a final report. Any additional analysis that may shed further light on important contraception and pregnancy issues may be performed following the principle tabulations.

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