

Supporting Statement B

Emergency Zika Package: Zika Postpartum Emergency Response Survey, Puerto Rico, 2017

Request for OMB approval of an Emergency ICR

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List of Abbreviations

CAPRZ	Contraceptive Assessment in Puerto Rico during Zika
CDC	Centers for Disease Control and Prevention
EOC	Emergency Operations Center
ICR	Information collection request
IIF	Information in identifiable form
IRB	Institutional review board
OMB	Office of Management and Budget
PRAMS	Pregnancy Risk Assessment Monitoring System
PIDS	Integrated Data Collection System
PRDH	Puerto Rico Department of Public Health
SPSS	Statistical Package for the Social Science
ZPER	Zika Postpartum Emergency Response Survey

1. Respondent Universe and Sampling Methods

Hospital-Based Survey of Mothers

The goal of the hospital-based sampling is to collect information that will be representative of all women having a live birth island-wide, and to stratify by region to sample a sufficient number of women in each of the 8 health districts to allow for regionally specific estimates, as well. The goal for the telephone follow-up is to be representative island-wide, but not stratified by region.

The hospital-based survey of mothers (**Attachment 7a, c** – English; **Attachment 7b, d** – Spanish) 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. According to 2016 birth data, there are 36 hospitals in Puerto Rico which meet this criteria, all of which will be invited to participate (**Attachment 10**). As all hospitals agreed to participate in the hospital-based survey for mothers in the first cohort (Emergency OMB approval, control # 0920-1127), it is anticipated that there will be significant interest among the hospitals in participation in development of Cohort #2. There is no age restriction among pregnant women recruited, so any women with a hospital birth during the data collection period will be eligible to participate.

Women who do not give birth in a hospital or in a hospital with more than 100 births per year will not be represented. In 2016, 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.

The sampling frame in this study will be 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.

Because there is particular interest from a public health perspective in making inferences by geographic region, a random sampling plan, stratified by health region, is used so that inferences about prevalence can be estimated with sufficient precision, both overall in Puerto Rico, and within selected geographic regions; eight geographic regions (Arecibo, Aguadilla, Bayamon, Caguas, Fajardo, Mayaguez, Metro, and Ponce) will serve as the sampling strata. Sampling will be further stratified by hospital, although proportional allocation will be used (each hospital within a region will have the same sampling fraction). All women giving birth on days designated as sampling days within each hospital will be selected for the study.

Survey data will be weighted according to known distributions, provided at the end of the study by the Demographic Registry office, 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.

A sample size of about 400 is necessary in each stratum to estimate a prevalence for a dichotomous variable with a reasonable precision of 5% and a confidence level of 95%, assuming an infinitely large

population size (N). We anticipate an 80% response rate based on the results from the 2016 hospital-based survey. Applying the finite population correction factor (FPC) in each strata and adjusting for an expected response rate of 80% results in an overall sample size of 2,760. This data collection will be pilot tested with 360 women for a total number of 3,120 respondents.

Hospital-Based Survey of Fathers

The hospital-based survey of fathers (**Attachment 8a** – English; **Attachment 8b** – Spanish) will target the partners of participants in the second cohort. All fathers of infant's whose mother was selected for the sample are eligible if they are present at the time of the mother's interview. It is anticipated that 60% of fathers will be present. No additional follow-up will be attempted for fathers who are not available at the time of the maternal interview.

Telephone Follow-up Survey

The telephone follow-up survey will target a subset of the original study participants in the first and second cohort (**Attachment 9a & c** – English; **Attachment 9b& d**– Spanish). The Puerto Rico vital registry office will match information from ZPER respondents with the birth certificate record of their baby. The list of original study participants who can be matched to a birth certificate record will serve as the sampling frame. Among original ZPER participants, a proportional sample by region will be drawn. All Zika positive women will be included.

A sample size of 1,068 is necessary to estimate a prevalence for a dichotomous variable with a reasonable precision of 3% and a confidence level of 95%, assuming an infinitely large population size (N). We anticipate a 60% response rate to the telephone follow-up based on the results from a postpartum follow-up survey conducted in Puerto Rico in 2014. Applying the finite population correction factor (FPC) and adjusting for an expected response rate of 60% results in an overall sample size of 1,535. The telephone survey will be conducted twice (once for each cohort), so the total number of respondents is 3,070.

A detailed description of the methods used to determine overall sample size and sampling methods for each of the surveys (Maternal Hospital-based Survey, Father Hospital-based Survey and Telephone Follow-up Survey) is included in **Attachment 10**.

2. Procedures for the Collection of Information

Hospital-based Survey of Mothers:

Data collected from women who have recently had a baby is an ideal population to capture experiences around the time of pregnancy, and sampling in hospitals eliminates the need to wait for processing of birth certificate records and eliminates the need to contact women after they leave the hospital. This approach was successful in 2016 for Cohort #1, and will be repeated. The sampling schedule will be provided by CDC prior to the initiation of the study. The sampling schedule is developed so that each region has a large enough sample to generate regional specific estimates for the indicators collected by the questionnaire. Field staff from PRDH will visit each hospital on the day designated by the sampling schedule, select the sample from the hospital delivery log, and enter the information onto a data form. This is the manner in which study participants are recruited. Each sampled mother will be assigned a

unique study ID that can later be used to link information from the birth log to information from the survey. 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 each day.

Prior to having new mothers and fathers complete the hospital-based surveys, each respondent will be provided with a written informed consent document (**Attachment 3a** – English; **Attachment 3b** – Spanish). The informed consent document may be read by the respondents themselves, or if they prefer it may be read to them by the field staff collecting the data. The forms will include information about the survey and the reason for its being conducted, including the potential for future data linkage; it will also inform mothers who agree to participate that they may be contacted for the telephone follow-up survey. 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 questionnaires will be translated into Puerto Rican Spanish. The questionnaires must be put onto computers and the data entry program written.

Hospital-based Survey of Fathers:

Experiences during pregnancy are influenced both by the mother and her partner. While understanding the experience of the woman during pregnancy is important, there is currently a gap in information available about Zika awareness and the use of measures to prevent Zika transmission by the male partners of pregnant women in Puerto Rico. Interviewing both mother and father at the same time has the added advantage of being able to link risk factors to the family environment, answer questions about the influence of partner behaviors on pregnancy outcomes, and assess level of awareness about the risk of Zika infection during pregnancy among men with pregnant partners. Further, it is efficient in terms of data collection resources to collect data from both parties during the same encounter.

Telephone Follow-up Survey:

While there are many advantages to a hospital-based survey, this also leaves a gap in information obtained about infant care and ongoing protection from Zika virus infection in the postpartum period, which is important in the context of Zika-affected infants receiving appropriate follow-up as soon as possible. For this reason, the hospital-based survey of mothers will be supplemented with a telephone follow-up survey in the early postpartum period (at 6-10 months postpartum for the first cohort and at 2-4 months for the second cohort).

For the telephone follow-up survey, each woman will receive a pre-letter informing her that she has been selected to participate and providing her the opportunity to opt out (**Attachment 4a** – English; **Attachment 4b** – Spanish). The letter will include a phone number which she can use to decline participation and any further contact. Women who do not opt-out, will be grouped into batches based on the birth date of their infant. Women with the oldest infants will be called first. A call sheet will be generated for each sampled mother. On the designated start date, the interviewers will begin calling the first batch of women, and will record information about call attempts on the call sheet. Once the

participant is on the phone, a consent script is read before initiating the questionnaire (**Attachment 5a** – English; **Attachment 5b** – Spanish).

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

For the hospital-based surveys of mothers, 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. This approach worked well when implemented in 2016 for Cohort #1, and the response rate was 81%. The few difficulties encountered were due to challenges following the sampling schedule by some field staff workers. To address this weakness for the data collection in 2017, the format of the sampling schedules will be simplified, additional training will be provided to the field staff, and regional supervisors will be hired to monitor field staff on a daily or weekly basis.

For the hospital-based survey, any father of a sampled women who is available at the time that the mother is being interviewed will be invited to participate. The procedures are anticipated to be the same. The men 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. Based on the presence of fathers in the hospital during the interviews in 2016, it is anticipated that 60% of fathers will be available. It is unknown what percentage of these fathers will be willing to participate in the survey, but an estimated 50% response rate for eligible fathers has been proposed.

For the telephone follow-up survey, a subsample participants from the hospital-based survey of mothers will be invited to participate. Sampled women will be mailed a letter prior to contact and will be offered the opportunity to decline participation prior to receiving any phone calls. The telephone survey will focus on topics specific to the postpartum period, minimizing the risk of recall bias. Women who do not opt-out, will be grouped into batches based on the birth date of their infant. Women with the oldest infants will be called first. On the designated start date, the interviewers will begin calling the first batch of women, and will record information about call attempts on the call sheet. Follow-up for a batch of women ends 30 days after the date of initiation. Telephone interviewers can make up to 15 call attempts to each working telephone number for each sampled women. Women who decline to participated are removed from the call list for further follow-up. The telephone response rates will likely be lower the longer after birth the contact is attempted given that contact information will be provided by the Demographic Registry.

4. Tests of Procedures or Methods to be Undertaken

The implementing organization will spend several weeks of training field staff workers on study procedures, use of the tablets, and use of the data entry system, including becoming familiar with the questionnaire content, and procedures for the telephone follow-up surveys. An additional 3-5 days of

pilot testing of the entire process will be conducted in each selected hospital. For the telephone follow-up surveys, 10% of the calls that each interviewer makes will be monitored by the project coordinator or other designated staff person, and further training will be provided when needed.

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 assist with development of the questionnaire. 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. Most of these questions for the maternal survey have already been developed and used in the information collection in 2016. Additional questions for the postpartum telephone follow-up questionnaire and the father's questionnaire will be needed, however. 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-four 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 may be performed following the principle tabulations.

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