Supporting Statement A

Emergency Zika Package:
Zika Postpartum Emergency Response Survey (ZPER), Puerto Rico, 2017

Request for OMB approval of an Emergency ICR

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- **Goal of the study:** To assess utilization of Zika virus prevention strategies and identify resource needs for pregnant and postpartum women and newborn infants. Information collected will be used by the Puerto Rico Department of Health (PRDH) to: 1) determine the need for further refinements in educational messaging and prevention strategies that were developed for pregnant women during the first season of the Zika outbreak; 2) assess gaps in access to and receipt of medical and social services for postpartum women and newborn infants potentially exposed to Zika and then assess changes achieved.

- **Intended use of the resulting data:** Information related to the ongoing needs pregnant and postpartum women and their infants during pregnancy and in the postpartum period will immediately inform messaging, communications, and education materials for women and their health care providers and will be used to evaluate gaps in resources and utilization. Information will also be used to assess access to and use of recommended health care services for pregnant and postpartum women, and their infants such as Zika virus testing during pregnancy, and screening and early intervention services for infants, including those who may have been affected by Zika virus infection during pregnancy.

- **Methods:** Puerto Rico Zika Postpartum Emergency Response (ZPER) will employ a hospital-based survey of mothers and fathers to obtain information on the prenatal period. A follow-up telephone survey in the postpartum period will be used to evaluate the ongoing needs of mothers and infants in the postpartum period.

- **The subpopulation to be studied**: The operational target population is all women delivering a live birth and their infants and partners in Puerto Rico.

- **How data will be analyzed:** Data will be used to informed the PRDH about the use of personal preventive measures to avoid Zika virus during pregnancy, any gaps in adherence to Zika testing protocols for pregnant women, the reach of medical and social services targeting postpartum women and Zika-affected infants, and the use of highly effective contraceptive methods in Puerto Rico. All of this information, collected at a population level, will be analyzed using software to generate estimates that are representative of each region and the territory as a whole. Overall and regional specific prevalence estimates will be generated to identify resource gaps and areas where there is a need for improvement.

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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. Circumstances Making the Collection of Information Necessary

This is a request for emergency OMB approval of the information collection, "Zika Postpartum Emergency Response Survey (ZPER), Puerto Rico, 2017." The requested length of approval for this emergency information collection request (ICR) from Office of Management and Budget (OMB) is 3 months. As more than 3 months are needed to complete this information collection, the Centers for Disease Control and Prevention (CDC) will pursue a formal ICR to immediately follow this submission. Authorizing legislation for this ICR comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment 1).**

In December 2015, the Puerto Rico Department of Health (PRDH) reported the first locally acquired (index) case of Zika virus disease in the United States. Since then, 38,733 cases have been confirmed in Puerto Rico, including 3,076 among pregnant women.[1] Because the most common mosquito vector of Zika virus, *Aedes aegypti*, is present throughout Puerto Rico, Zika virus transmission is ongoing. The island has been designated at the highest level of risk according to a 3-tiered Zika virus infection risk scale developed by CDC's Emergency Operations Center (EOC).

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 infection during pregnancy. After review of the available evidence, CDC concluded that Zika virus infection during pregnancy is a cause of microcephaly and other severe brain defects. With no available vaccine or medication to prevent Zika virus infection, educational efforts are needed to promote awareness of potential outcomes, prevention strategies, recommendation for clinical care and appropriate follow-up and care for newborns potentially exposed during pregnancy.

A rapid hospital-based assessment of recently postpartum mothers was conducted in Puerto Rico during the fall of 2016 (ZPER, OMB control # 0920-1127). This survey provided important information on prenatal experiences (e.g., knowledge of prevention strategies, sources of information, behaviors of pregnant women and their partners related to sexual and vector-based transmission, discussions with providers, testing for Zika, and healthcare needs during pregnancy). The information was rapidly used by the Puerto Rico Department of Health (PRDH) and the CDC's EOC to develop clinical guidance, refine communication messages, and determine resource gaps. In particular, the data highlighted that fewer than half of women consistently use measures to protect themselves from mosquito bites such as daily use of mosquito repellent and protective clothing, and that only a third of women consistently used measure to avoid sexual transmission throughout pregnancy. These finding were used by PRDH to modify and enhance messaging and interventions targeting pregnant women to promote the use of condoms and mosquito prevention strategies. Additionally, the data collected indicated that although most prenatal care providers counsel women about Zika virus, 20% of women did not receive a recommended Zika virus test in the first or second trimester and that considerable variation existed by health region and maternal characteristics. PRDH has used this information to strengthen regional efforts to refine prevention messages and resources, and to ensure provider adherence to testing guidelines.

As the outbreak continues, there is a need to reassess the effectiveness of emergency response efforts from the first season and to determine where additional efforts and resources are needed in subsequent

[1] http:/www.salud.gov.pr/Estadisticas-Registros-y-Publicaciones/Informes%20Arbovirales/Reporte%20ArboV%20semana%205-2017.pdf

seasons. The current information collection request proposes to do this by administering the same hospital based-survey to a second cohort of women during their delivery hospitalization.

In addition to the need for follow up data to assess current prevention and testing levels during pregnancy, there is a need to assess the receipt of services after pregnancy -- during the early postpartum and infant period. In January 2017, The Health Resources and Services Administration (HRSA) provided funding to various agencies in the PRDH to address the issues of screening, access, and coordination of care for women, children and families. Funded agencies have the potential to fill a critical gap in services, given the intensive care that is needed during the early postpartum period among infants who have been affected by Zika. However, there are currently no population-based data to identify where there are gaps in health care for young infants born to women in Puerto Rico who were pregnant in the first year of the Zika outbreak. Clinical data are available, but they are limited to those who seek and receive services. Further, because the previous data collection (ZPER, OMB control # 0920-1127) occurred during the delivery hospitalization, it only provided information about services received during pregnancy, not the postpartum and early infant period.

To fill this information gap, in January 2017, the Puerto Rico Department of Health was funded by the Centers for Disease Control to collect population-based data to inform these efforts to provide services in the postpartum and early infant period. For this purpose, it is proposed that the first cohort of mothers, who were previously surveyed about their experiences during pregnancy, be re-contacted by phone 2-10 months after delivery to assess their access to and utilization of postpartum health care services for themselves and their infants, and their continued use of measures to avoid Zika infection, including use of postpartum contraception to prevent rapid repeat pregnancies that are unintended and might otherwise be affected by Zika. Collecting this information rapidly will be critical. CDC recommendations emphasize the immediate need for services among affected infants, many of which are supposed to be delivered during the first 2 months of life.[2] A rapid assessment looking back at the early infant period as well as ongoing use of services recommended during the first year, is needed rapidly to respond to gaps in provision of early services for vulnerable infants. This information will also be collected from the second cohort of mothers described above to refine efforts based on the first round to data collection to fill gaps in services for the postpartum and early infant period.

Finally, because fathers play a critical role in the health and well-being of their infants, there is a need to assess their knowledge and contribution to prevention efforts and use of recommended care during pregnancy. However, interviews of fathers were not included in the previous data collection (ZPER, OMB control # 0920-1127). Therefore, the current information collection request proposes to interview fathers who are present when the second cohort of mothers is contacted during their delivery hospitalization to assess their contribution to prevention efforts and healthcare utilization during pregnancy.

2. Purpose and Use of Information Collection

The objectives of the current information collection request are outlined below. In summary, the data from this study will be a unique source of information that can supplement clinical data demonstrating the reach of services for all pregnant and postpartum women, as well as their infants. Currently no population-based information exists about postpartum health and health care for young infants born to women in Puerto Rico who were pregnant in the first year of the Zika outbreak, or from fathers. Table 1, which follows the statement of objectives, summarizes the way data collection results will be used.

[2] https://www.cdc.gov/mmwr/volumes/65/wr/mm6533e2.htm?s_cid=mm6533e2_w.

Objective 1: To conduct a second hospital-based survey to assess the use of prenatal services and prevention measures during pregnancy, as promoted through emergency response efforts developed during the first Zika outbreak season in Puerto Rico, and to determine where additional refinement and resources are needed for subsequent seasons.

During the fall of 2016 information was collected from an initial cohort of women (Cohort #1) to assess their experiences during pregnancy and to guide emergency response efforts during the first season (ZPER, OMB control # 0920-1127). Under the current information collection requests, we propose to collect information from a second cohort (Cohort #2) to assess if uptake of prevention strategies increased and what refinements may be needed for subsequent seasons to improve care and prevention of Zika during pregnancy.

Specific topics to be addressed will include:

- Respondent knowledge and awareness of Zika virus transmission during pregnancy
- Prenatal care counseling and testing related 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

Objective 2: To contact women previously surveyed about their experiences during pregnancy to assess the use and availability of postpartum and early infant services. Since women who were Zika positive during pregnancy are all included in this follow-up survey, it will be particularly useful to highlight successes and gaps in access to resources available through recent HRSA funding to PRDH, and to inform guidelines for pediatric providers related to caring for infants potentially exposed to Zika virus.

Because the initial survey of women in Cohort #1 was hospital-based, it did not capture information about postpartum and early infant experiences. A follow-up telephone survey will therefore be used to contact women from Cohort #1 during the postpartum period (2-10 months after delivery). Information from Cohort #1 will be used to make an initial determination on resources needs and allocation and the design of prevention messages. Women from Cohort #2 will also be contacted 2-10 months after delivery to assess the need for further refinement.

Specific topics to be addressed will include:

- Infant health conditions related to Zika virus
- Use of health services for infants
- Postpartum counseling by health care providers
- Use of social services postpartum
- Practices to prevent vector-borne transmission after pregnancy
- Use of contraception postpartum

Objective #3: To assess the contribution of fathers to prevention and service utilization during pregnancy and to assess how men can be included in messages and prevention efforts during pregnancy.

This survey will also be hospital-based and will interview men who are present with the mother during her delivery hospitalization. Because fathers are no longer accessible through a hospital-based survey for Cohort#1, this objective will be limited to Cohort #2.

Specific topics to be addressed will include:

- Respondent knowledge and awareness of Zika virus transmission during pregnancy, including trusted sources of information
- Respondent counseling and testing relate to Zika virus
- Practices to prevent vector-borne transmission during partner's pregnancy

Objective	Study Phase	Findings	Impact
#1	Cohort 1 & 2 – In-hospital survey of new mothers	From Cohort #1: • Most women were aware of Zika virus and concerned about infection during pregnancy • Most women received advice from prenatal care providers about avoiding Zika virus • Over three quarters were tested for Zika by their provider in the 1st or 2nd trimester • Fewer than half of women used measures to prevent mosquito bites daily • Fewer than half of women consistently used measures to prevent sexual transmission during pregnancy	• Informed PRDH about need for enhanced messaging about personal preventive measures during pregnancy • Informed PRDH about gaps in adherence to testing protocols across the island • Led to the implementation of an educational intervention for postpartum women in the hospital following delivery • Cohort #2 data collection allows for comparison with 2016, and assessment of any improvements in adherence to use of recommended prevention & testing measures by women and providers
#2	Cohort 1 & 2 – Telephone follow-up	TBD	• Will inform PRDH about the reach of medical and social services targeting postpartum women and Zika-affected infants • Will inform initiatives that have been implemented to increase access to highly effective contraceptive methods in Puerto Rico • Cohort #2 data collection allows for comparison with 2017, and assessment of any improvements

			in provision of services to women and infants, as well as use of effective contraception
#3	Cohort 2 – In-hospital survey of fathers	TBD	• First assessment of the role of male partners in supporting Zika prevention efforts of their pregnant partners; this information can be used to create messaging for the entire family, which could be an approach that enhances protective practices for pregnant women

- Practices to prevent sexual transmission of Zika virus during pregnancy, and contraception use prior to and after pregnancy, including factors that influence use
- Communication with wife or partner related to Zika virus and involvement in prenatal care visits

Table 1.

3. Use of Improved Information Technology and Burden Reduction

The hospital-based surveys will be completed on electronic tablets or paper forms. Each field staff worker will have one tablet, so use of tablet versus paper will depend on the number of participants 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.

Data collected from the follow-up telephone interviews will also be entered into the 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 PRDH for this project.

For the hospital-based surveys, one-hundred percent of burden hours will be incurred by respondents during the delivery hospitalization. For the telephone follow-up survey, one-hundred percent of the burden hours will be incurred during the telephone interview. The minimum number of questions needed to assess behaviors and experiences related to Zika virus exposure are collected.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of any other systematic collection of the information described herein. The information collected through this request will be used by the Puerto Rico Department of Health, CDC, HRSA and other federal agencies involved in the Zika Emergency Response and will provide the only population-based data on pregnant women and their infants – 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. It will be critical for understanding adherence to prevention strategies and assessing the availability, accessibility and utilization of postpartum and newborn services – especially for women and infants who may have been affected by Zika.

The data collected through the follow-up telephone surveys in the postpartum period will complement other Zika emergency response activities currently underway. Various federal and local agencies are working to strengthen systems of support and comprehensive health care for women, children and families who are facing long-term health impacts from the Zika virus. This information will fill a critical gap, as there is currently no other source of population-based information about health care for pregnant and postpartum women or their young infants in Puerto Rico during the Zika outbreak. Although clinical data are available, they are limited to those who seek and receive services.

Previously CDC collected information in the hospital-based survey for mothers to address topic related to the prenatal period **(OMB control # 0920-1127**). Because this survey was conducted during the delivery hospitalization, it only assessed experiences during pregnancy. Information collected from the telephone follow-up survey will provide new key information about experiences in the postpartum period. The new information will allow for collection of information on services received by infants, not previously available during the hospital-based study when they were only 1-2 days old. Topics will be related to utilization of Zika virus prevention strategies and resource needs for newborn infants and postpartum women, along with the effectiveness of efforts to prevent rapid repeat pregnancies that are unintended among postpartum women. In addition, data is needed to assess the extent to which interventions from the first outbreak season have been effective at improving outcomes and prevention efforts among pregnant women and the extent to which they need to be refined. Further, the hospital-based survey data from fathers will be unique in evaluating their contribution of maternal knowledge and Zika prevention.

The proposed information collection is also unique in that it will be the only source of data on Zika prevention strategies among pregnant women that is representative of this population by region and overall for Puerto Rico. Other studies focus on subsets of the population of pregnant women, such as those participating in clinical interventions or social programs. This is in contrast to information from the **Zika Emergency Package V: Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections (OMB control #0920-1118)**, which only included women who were WIC participants and received interventions from the WIC program.

Emergency Zika Package IV: Assessment of Contraceptive Use and Needs, Puerto Rico (CAPRZ), 2016 (OMB control #0920-1114) also collected population representative information on women of a similar age (18-49 years), and also included question on contraceptive use and preventing sexual and mosquito born Zika transmission. However, given the low prevalence of respondents in this previous survey who were pregnant at the time of interview (2.0%), CAPRZ has been unable to produce reliable estimates for women who are pregnant or recently postpartum. Further, the CAPRZ survey did not include women aged <20 years; this is an important gap given the rate of teen births is high in Puerto Rico. Finally our current request will fill a gap in assessing effort to improve contraception use in the immediate postpartum period, specifically for highly effective contraception. For example, provision of immediate postpartum long acting reversible contraception (LARC) improves birth spacing, and reduces barriers such as returning for postpartum visit for contraception care and discontinuation of public insurance coverage.

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**]. The data collection proposed in this ICR application is not overlapping, but rather can inform ongoing refinement of these campaigns.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small business or other small entities.

6. Consequences of Collecting the Information Less Frequently

This information collection is specifically to assess various aspects of maternal behaviors and experiences as they relate to prevention strategies and access to resources related to Zika virus exposure among infants, prenatal and recently pregnant women in Puerto Rico. The data collection is needed to assess the effectiveness of immediate response efforts and to identify where there are further gaps in resources, knowledge, and adherence to prevention strategies and clinical guidelines. Collection of data less frequently would prohibit calculation of these needed estimates and inhibit the utility of the data.

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 60-day Federal Register Notice was published in the Federal Register (82 FR 18640) on April 19, 2017 to make the public aware of this proposed information collection (**Attachment 2**). No public comments have been received. Because this is a request for an Emergency Clearance to collect time sensitive data, CDC requests OMB review without waiting for the 60-day comment period to expire. As more than six months are needed to complete this information collection, CDC will pursue a formal ICR as soon as emergency approval is granted. For this formal, non-emergency ICR, the 60-day FRN will be followed by a 30-day FRN and ICR application requesting three years of OMB clearance.

HRSA and local collaborators at PRDH have been involved in discussions regarding the design of the survey and methodology to inform ongoing Zika response efforts, ensure cultural appropriateness and community relevance in all aspects of data collection, including recruitment efforts, instruments, and consent processes. Having successfully completed the first hospital-based survey of mothers, PRDH and CDC are evaluating the experience to make any minor modification that may be needed. CDC is currently working closely with PRDH colleagues to align English and Spanish versions of the all documentation and procedures of the project. There are no unresolved problems with outside collaborators.

9. Explanation of Any Payment or Gift to Respondents

For the hospital-based survey of mothers, participants will be offered a crib net and a calendar with developmental milestones for their infant as a token of appreciation. For the hospital-based surveys of fathers, the family will receive a swaddle blanket, burp towels, or another similar gift that can be used for the baby as a token of appreciation. For the telephone follow-up survey of mothers, diapers, onesies, or other baby supplies, insect repellent, or a voucher of equivalent value, will be offered as a token of

appreciation. In the event that a baby has died, insect repellent, an adult size mosquito net, or other small token will be provided. In general, providing a token of appreciation has been found to be important for encouraging participation in federal surveys, especially for more reluctant responders.[3,4,5] For participants in this survey, who have a newly born infant, increasing motivation to participate is particularly salient: this survey focuses on a special population during a limited time when parents time is limited such that participating in even simple activities is constrained by lifestyle changes, financial constraints, childcare duties, and fatigue.[6,7]

10. 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. Names will be collected for the purpose of later linking survey responses to information collected by the PRDH in their vital records system. Once linked to the birth certificate, additional linkages may also be completed for data PRDH has related to testing and receipt of services. Later linkage of the data will allow for analysis of maternal and infant characteristics and outcomes such as birth defects that are collected by the birth certificate, but not the survey. The participant name will be kept in a separate file from the survey responses. Completed surveys and any files with personal identifiers must be kept in a locked file cabinet or a locked room; access to these files must be limited to authorized personnel. All electronic files will have restricted access; the operations tracking software will be password-protected. Backup data files will also be secured.

Each survey participant with be assigned a unique identification number. No additional personal identifying information will be included in any analytic data set. CDC will only include aggregate and summary information in reports and will not include information 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 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

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[3] Singer E, Kulka RA. (2002). Paying Respondents for Survey Participation. In Studies of Welfare Populations: Data collection and research issues.105-28. Washington DC: National Academy Press.

[4] Singer2Singer E, Ye C. (2013) The Use and Effects of Incentives in Surveys. Annals of the American Association of Political and Social Science, 645:112-141.

[5] Berry SH, Pevar J, Zander-Cotugno M. Use of Incentives in Surveys Supported by Federal Grants. Rand Corporation, March 2008.

[6] Nicklas JM, Zera CA, Seely EB, et al. (2011). Identifying postpartum intervention approaches to prevent type 2 diabetes in women with a history of gestational diabetes. BMC Pregnancy and Childbirth 11:23.

[7] Van Ryswyk EM, Middleton PF, Hague WM, Crowther CA (2015). Women's views on postpartum testing for type 2 diabetes after gestational diabetes: Six month follow-up to the DIAMIND randomised controlled trial. Prim Care Diabetes. 2015 Aug 27. pii: S1751-9918(15)00100-X. doi: 10.1016/j.pcd.2015.07.003.

also inform potential participants that they may be contacted for the telephone follow-up survey. Respondents who agree to participate in the hospital-based survey for mothers will be given the opportunity to opt out of selection for the telephone follow-up survey (**Attachment 4a** – English; **Attachment 4b** – Spanish), in which case they will not be re-contacted. When participants who have agreed to be re-contacted are called for the telephone follow-up survey, verbal informed consent will be obtained over the telephone (**Attachment 5a** – English; **Attachment 5b** – Spanish). For both the hospital-based and telephone follow-up surveys, potential respondents will be informed that participation is purely voluntary.

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

IRB Approval

This data will be collected under the approved CDC IRB protocol for the Pregnancy Risk Assessment Monitoring System (**Attachment 6**). The survey is funded and operated through the Puerto Rico PRAMS project as a supplemental activity to the regular PRAMS surveillance. It uses a revised methodology to more rapidly survey women from the same target population as PRAMS (women with a recent live birth). The CDC IRB determined the study to be not greater than minimal risk to subjects. PRDH was awarded funding as a PRAMS site, with data collection slated to begin June 2017. CDC and the Puerto Rico Department of Health will coordinate sampling so that PRAMS and ZPER data collection do not contact the same women.

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 women. Sensitive questions are essential to meeting the goals of this information collection. During the informed consent process, participants will be notified of the types of the questions that will be asked and will also be notified that they may decline to discuss any of the topics or decline to answer any question without penalty. Steps to protect the privacy of information provided by respondents is included in Section A10.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Previously, during the initial Zika outbreak in Puerto Rico, 2,364 women in the first cohort completed of the hospital-based survey for mothers (OMB control # 0920-1127) (**Attachment 7a** – English paper; **Attachment 7b** – Spanish paper; **Attachment 7c** – English tablet; **Attachment 7d** – Spanish tablet). For the second cohort, 2,760 women will be asked to participate in the hospital-based survey for mothers. An additional 360 women will be contacted during the one week pilot phase prior to the initiation of the hospital-based study for a total of 3,120 participants. The average time-burden will be 25 minutes per response for a total of 1,300 burden hours.

Fathers who are present at the time the second cohort of mothers complete the hospital-based survey will be asked to complete a separate hospital-based survey for fathers (**Attachment 8a** – English; **Attachment 8b** – Spanish). Given the estimate that the father will be available 60% of the time, 1,656 men will be asked to participate. An additional 216 men will be contacted during the one week pilot

phase prior to the initiation of the hospital-based study for a total of 1,872 participants. The average time-burden will be 15 minutes for a total of 468 burden hours.

Of the first cohort of women who complete the hospital-based survey for mothers, 1,535 will be asked to complete the telephone follow-up survey (**Attachment 9a&c** – English; **Attachment 9b&d** – Spanish) and 1,535 of the second cohort will be asked to complete this survey for a total of 3,070 telephone surveys completed. There will be no pilot testing for this data collection. The average time-burden for the telephone follow-up survey is 15 minutes, for a total of 768 burden hours.

The overall annualized burden requested under this current ICR totals is 2,536.

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	Hospital-based survey for mothers **(Attachment 7a,b, c, d)**	3,120	1	25/60	1,300
Fathers with recently born infants	Hospital-based survey for fathers (**Attachment 8a,b**)	1,872	1	15/60	468
Women with live births 2-10 months prior	Telephone follow-up survey **(Attachment 9a,b)**	3,070	1	15/60	768
Total					2,536

B. Estimated Annualized Burden Costs

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

The annual response burden cost is estimated to be $49,782. 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). 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 births	Hospital-based survey for mothers **(Attachment 7a,b, c, d)**	1,300	$23.23	$30,199
Fathers with recently born infants	Hospital-based survey for fathers (**Attachment 8a,b**)	468	$23.23	$10,872
Women with live births 2-10 months prior	Telephone follow-up questionnaire **(Attachment 9a,b,c,d)**	768	$23.23	$17,841
Total				$58,911

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

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

14. 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.

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
Total					$400,587

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

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 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 or peer-review journal 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 survey into Spanish, preparation of training

materials, programming of survey for data entry and editing, establishing contact with participating hospitals, and obtaining approvals.

Cohort I Telephone Follow-up Survey

- April 2017 - Training of telephone interviewers
    - Who: PRDH
- April 2017 – June 2017 - Begin interviewing 1,434 follow up surveys for cohort 1 respondents (representative sample of women who participated the first round of the hospital-based sample); data collection will continue for 90 days after initiated
    - Who: PRDH
- April 2017 - Development of interim and final data analysis plan
    - Who: CDC Division of Reproductive Health, PRDH, and CDC EOC
- April 2017 – June 2017 - Interim cleaning, preparation of data for analysis begins
    - Who: CDC Division of Reproductive Health
- September 2017 – October 2017 - Data weighting and processing complete; release of first set estimates per analysis plan
    - Who: CDC Division of Reproductive Health and CDC EOC
- November 2017 – December 2017 - Preparation of final assessment reports in Spanish and English
    - Who: CDC Division of Reproductive Health and PRDH

Cohort II Hospital-based Survey (for Mothers & Fathers)

- June 2017 – August 2017 – Training staff, establishing agreements with hospitals, preparing materials
    - Who: PRDH
- September 2017 – November 2017 – Data collections for maternal and paternal hospital –based survey conducted
    - Who: PRDH
- September 2017 – November 2017 - Interim cleaning, preparation of data for analysis begins
    - Who: CDC Division of Reproductive Health
- December 2017 – Data weighting and processing complete; Release of first set estimates per analysis plan in English and Spanish
    - Who: CDC Division of Reproductive Health, PRDH, and CDC EOC

Cohort II Telephone Follow-up Survey

- November 2017 – February 2018 - Begin interviewing 1,434 respondents (representative sample of women who participated the first round of the hospital-based sample); data collection will continue for 90 days after initiated
    - Who: PRDH
- November 2017 – February 2018- Interim cleaning, preparation of data for analysis begins
    - Who: CDC Division of Reproductive Health
- April 2018 – May 2018 - Data weighting and processing complete; Release of estimates per analysis plan in English and Spanish
    - Who: CDC Division of Reproductive Health and PRDH

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.