

Zika Reproductive Health Call-Back Survey (ZRHCS), Puerto Rico, 2017

New Information Collection Request

Supporting Statement A

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- **Goal of the study:** To assess, on a population-level, the current utilization of Zika prevention strategies targeted at women of reproductive age (18-49 years) in Puerto Rico, and determine the need for further refinements in educational messaging and allocation of resources, as established during the first season of the Zika outbreak.
- **Intended use of the resulting data:** Information collected will be compared to 2016 survey data (OMB Control No. 0920-1114) to inform Zika emergency response planning

1. Circumstances Making the Collection of Information Necessary

This is a request for a new information collection to continue the emergency information collection, “Emergency Zika Package: Zika Reproductive Health Survey, Puerto Rico, 2017,” approved by the Office of Management and Budget (OMB) in July (OMB Control No. 0920-1188). This emergency clearance expires October 31, 2017. CDC requests an additional year of clearance to continue this project. Authorizing Legislation for this information collection comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment 1**).

In May 2015, the World Health Organization reported the first local mosquito-borne transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. In response to the Zika virus outbreak and evidence that Zika virus infection during pregnancy is a cause of microcephaly and other adverse pregnancy and infant outcomes, CDC’s Emergency Operations Center was activated at its highest level on February 8, 2016. To date, local transmission has been identified in at least 50 countries or territories in the Americas. Within the United States, Puerto Rico has reported the highest number of Zika virus cases – as of June 2017, the Puerto Rico Department of Health (PRDH) has reported more than 40,000 cases of Zika virus infection, including 3,757 cases in pregnant women.^{1,2}

Given the adverse pregnancy and birth outcomes associated with Zika virus infection during pregnancy and the current lack of a vaccine, it is important for women who are at risk of becoming pregnant unintentionally, or who are planning a pregnancy, to be knowledgeable about the potential outcomes and to effectively practice behaviors for preventing mosquito-borne and sexual transmission of Zika. Additionally, among those women who wish to delay or avoid pregnancy, helping them to avoid unintended pregnancies that might otherwise be affected by Zika is a key countermeasure. This later countermeasure is especially important in light of historically high unintended pregnancy rates in Puerto Rico as compared to the United States overall.³

During the first season of the Zika outbreak, to assess adherence to recommended prevention behaviors among women of reproductive age (18-49 years), CDC, in collaboration with the PRDH, conducted the survey “Assessment of Contraceptive Use and Needs, Puerto Rico, 2016” (CAPRZ; OMB Control No. 0920-1114) during July-November 2016. This population representative survey found that only 2% of women of reproductive age were pregnant, thus illustrating the survey reached a unique population not covered by surveys of pregnant and recently postpartum women (e.g., Zika Postpartum Emergency Response Survey, Puerto Rico, 2016; OMB Control No. 0920-1127). Through this assessment including all women of reproductive age, the 2016 CAPRZ survey found 22% of women in this group used mosquito repellent every day and 8% wore long sleeves and pants; among sexually active women, 22% used a condom every time they had sex, and 70% never used a condom. Among those who were sexually active and otherwise capable of pregnancy,⁴ 45% relied on permanent contraceptive methods, while 13% used a most or moderately effective method obtained through a healthcare provider;⁵ 14%

¹ <https://www.cdc.gov/zika/intheus/maps-zika-us.html>.

² <http://salud.pr.gov/Estadisticas-Registros-y-Publicaciones/Informes%20Arbovirales/Reporte%20ArboV%20semana%2021-2017.pdf>

³ Estimates from 2011-2011 indicate 65% of pregnancies in Puerto Rico were unintended, compared to 45% for the US overall: the proportion of unintended pregnancies in Puerto Rico has been 65% vs. 45%; Emerg Infect Dis. 2017 Jan;23(1):74-82; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5176229/>.

⁴ Excludes women who report they were currently pregnant/seeking pregnancy, had had a hysterectomy, had undergone menopause or had been trying to get pregnant for >2 years.

⁵ Permanent methods include tubal sterilization and male partner’s vasectomy ($\leq 1\%$ annual failure); reversible methods obtained from a healthcare provider include intrauterine devices and implants ($\leq 1\%$ annual failure), and shots, pills, patch, vaginal ring and diaphragm (6-10% annual failure). This compares to > 18% failure with less effective methods that do not need to be obtained from a healthcare provider: <https://www.ncbi.nlm.nih.gov/pubmed/21477680/>.

used no contraceptive method at all. Among women who reported being very worried about having a baby with a birth defect, only 4% changed their contraceptive use patterns.

The findings from this survey were of critical importance to the PRDH, and were immediately used for targeting messages on a territory wide and regional level for non-pregnant women of reproductive age about the importance of behaviors to prevent mosquito-borne and sexual transmission of Zika. Additionally, these findings have been used to inform and target services provided through the Zika Contraception Access Network (Z-CAN), a privately-funded program launched in 2016 to increase access to reversible contraceptive methods among reproductive-aged women in Puerto Rico who choose to delay or avoid pregnancy as a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes. As part of this program, contraceptive use was monitored through “Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN; OMB Control No. 0920-170A). However, the evaluation only collected information specific to experiences of program participants and serving clinics, and cannot be used to assess gaps in contraceptive availability and barriers to access among women who have not been served through this program.

Given that Puerto Rico has continued to have more cases of Zika virus infection than in any other US state or territory, information on adherence to prevention strategies for mosquito-borne and sexual transmission of Zika is needed to assess the effectiveness of emergency response efforts from the first season and to further refine and determine where additional efforts and resources are needed. This is particularly important as health officials and clinicians in Puerto Rico have expressed concern about complacency among women of reproductive age in relation to Zika virus, despite the causal link between infection during pregnancy and devastating birth defects. It is therefore important to identify populations in which complacency is occurring. In addition, data are needed to assess population levels of contraceptive use in Puerto Rico and whether there has been an increase in use of effective methods following implementation of the Z-CAN program, given that the program itself has only obtained information from participants. The current information collection request proposes to do this by administering the CAPRZ survey (OMB Control No. 0920-1114) to a second cohort of reproductive age women. Given the original CAPRZ survey was conducted in July-November 2016, the timing of this data collection is meant to coincide with the timing of the survey in 2016 to aid in comparing the data from the two surveys. Under emergency approval (OMB Control No. 0920-1188) data collection has been ongoing for the second cohort since July 2017. This request is to continue information collection for those who agree to participate through December 2017.

2. Purpose and Use of Information Collection

This assessment will be designed to answer several important questions about women of reproductive age (18-49 years) in Puerto Rico who are not within the small proportion who are currently pregnant or recently postpartum. This information will be used to assess, on a population-level, the current utilization of Zika prevention strategies targeted at women in this age group, and determine the need for further refinements in educational messaging and allocation of resources, as established during the first season of the Zika outbreak. It will address questions related to knowledge of Zika transmission and sources of information, use of prevention behaviors related to mosquito-borne and sexual transmission of Zika, contraceptive use and barriers to accessing contraception, and pregnancy intentions and changes in plans for childbearing in relation to Zika in Puerto Rico. These questions include:

Knowledge of Zika:

- Where do women obtain information about Zika?
- Do women know the modes of Zika transmission?

Zika Prevention Behaviors:

- What behaviors do women use to prevent mosquito transmission of Zika?
- Has there been a change in the use of these behaviors since 2016? Does this depend on women's pregnancy intentions and the effectiveness of contraceptive methods used?
- Do sexually active women use condoms to prevent sexual transmission of Zika? Has there been a change in the use of these behaviors since 2016?

Contraceptive use

- What is the contraceptive prevalence rate among women/couples (overall and broken out by geographic, demographic, and socioeconomic characteristics), and has this changed from 2016?
- What is the mix of contraceptive methods that is being used, and has this changed from 2016?
- What is the level of unmet need for family planning methods, and has this changed from 2016?
- What is the rate of unintended pregnancy and the proportion of pregnancies reported to be unintended, and has this changed from 2016?
- What are the reasons that women who do not desire to become pregnant are not using contraception? (i.e., what are the main barriers to contraceptive use?) Have these reasons changed from 2016?
- What contraceptive methods do women/couples desire to use, and has this changed from 2016?

Pregnancy intentions and changes in relation to Zika

- What do women know about the effects of Zika on births and pregnancy and how have their knowledge and opinions affected desires and behaviors related to pregnancy and contraception, and has this changed from 2016?
- Has Zika affected women's reproductive health behaviors and pregnancy intentions?

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via telephone. Given the need for a sample large enough for statistical analyses, telephone surveys offer a cost effective method of data collection. Interviewers will use Computer Assisted Telephone Interview (CATI) software to enter data directly into a database. Use of CATI software promotes efficiency in two ways: skip patterns can be programmed to route respondents only to questions that they are eligible to answer, and real-time quality control checks can be used to eliminate some errors which may have been caused by manual data entry procedures.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of any other systematic collection of the information described herein with a specific focus. Below is a list of similar projects and how the data collected for the Zika Reproductive Health Call-Back Survey in Puerto Rico will fill the gaps not addressed by these existing efforts.

Ongoing projects in the CDC Zika Response and how the Zika Reproductive Health Call-Back Survey (ZRHCS) fills gaps not addressed by these existing efforts		
Project	Objectives and Population	Contribution added by ZRHCS in Puerto Rico
Assessment of Contraceptive Use and Needs, Puerto Rico, 2016 (CAPRZ) (0920-1114)	CAPRZ studied various aspects of Zika prevention and related reproductive health topics among women of reproductive age in Puerto Rico during the first season of the Zika outbreak. Topics included use and barriers to accessing contraception among women wishing to avoid or delay pregnancies, and adherence to strategies for preventing mosquito-borne and sexual transmission of Zika.	The ZRHCS in Puerto Rico will provide comparable data during the same season (July-November) in 2017 and will be used to determine the need for further refinements in educational messaging and allocation of resources, as established during the first season of the Zika outbreak.
Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN) (0920-170A)	This information collection is an evaluation of Z-CAN, a program designed to address access barriers to contraception in Puerto Rico. The information collected through this program is specific to experiences of program participants and serving clinics.	The ZRHCS in Puerto Rico is needed to collect population representative data that can be used in a comparison of contraceptive use patterns among Z-CAN participants and the general population of reproductive age women.
Zika Postpartum Emergency Response Survey, Puerto Rico, 2016 (ZPER) (0920-1127)	The ZPER study population included only women who recently gave birth in Puerto Rico, and is intended to inform decision-making regarding promotion of protective behaviors against Zika exposure during pregnancy.	Given that only 2% of women in CAPRZ (0920-1114) were pregnant, the current information request will focus on a distinct population. The ZRHCS in Puerto Rico will study women of reproductive age, regardless of prior or current pregnancies—and is anticipated to also have a very small number of pregnant women included.
Behavioral Risk Factor Surveillance System (BRFSS) (0920-1061)	BRFSS surveys adults in participating jurisdictions, on a variety of health conditions, indicators, and behaviors. Currently, there is an optional 3 question module to assess contraceptive use prevalence.	The ZRHCS in Puerto Rico uses the main BRFSS to sample eligible respondents via a recruitment script administered to women 18-49 years of age at the end of the core BRFSS survey in Puerto Rico. The BRFSS does not have any of the questions ZRHCS has on barriers to accessing contraception and other reasons for nonuse, nor does it have information on Zika knowledge and behaviors related to prevention of mosquito-borne or sexual transmission of Zika.
Zika virus persistence in body	The objective of this information collection is to assess the	Not applicable – ZRHCS does not propose to address Zika

fluids of patients with Zika virus infection in Puerto Rico (ZIPER Study) (0920-1140)	length of time Zika may persist in body fluids. The study population is residents of Puerto Rico testing positive for Zika virus infection and household contacts of cases.	virus persistence; rather ZRHCS addresses prevention behaviors not addressed by ZIPER.
The Effect of Community-Wide Vector Control Initiatives on Zika Virus Transmission in Puerto Rico, 2016 (0920-1137)	The objective of this information collection is to conduct household-based cluster investigations in areas of Puerto Rico with and without ongoing community-wide vector control. The study population is persons with suspected Zika virus disease that have laboratory evidence of current or recent Zika virus infection in Puerto Rico.	Not applicable – ZRHCS does not propose to address community-wide vector control; rather ZRHCS addresses personal prevention behaviors.
Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease (0920-1136)	The objective of this information collection is to determine knowledge, attitudes, and practices related to a new Domestic Readiness Initiative on Zika Virus Disease being launched in select regions of the United States. It assesses awareness of campaign activities, how people perceive Zika as a health risk, and assess their uptake of recommended health behaviors, such as applying insect repellent, using condoms, and wearing long-sleeved clothing. The study population includes residents of four locations: Puerto Rico; Miami, FL; Houston, TX; and Mississippi.	The ZRHCS in Puerto Rico is focused on reproductive health behaviors and is targeted specifically to women of reproductive age. While the survey includes some similar question on assessing knowledge and sources of information about Zika and use of behaviors to prevent mosquito-borne and sexual transmission, the questions on ZRHCS are designed to match the CAPRZ survey (0920-1114) and will be matched in terms of age of women and the season. Moreover, ZRHCS contains questions specific to its target population of women of reproductive age, which assess contraceptive prevalence, barriers to contraceptive access, and changes in pregnancy intentions or planning.
US Zika Pregnancy Registry (USZPR) (0920-1143)	Study population includes only pregnant women in the US with laboratory evidence of Zika virus infection, excluding Puerto Rico; USZPR focuses on clinical outcome data.	The study population for ZRHCS in Puerto Rico is women of reproductive age, and will include very few pregnant women (estimated to be 2% from previous population-based survey) and focuses on behavioral and prevention data.
Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus infections (0920-1118)	The objective of this information collection is to assess the delivery and effects of interventions implemented in Puerto Rico to protect pregnant women from Zika virus infections. The study population is pregnant women living in Puerto Rico enrolled in the federal supplemental nutrition program for Women, Infants, and Children (WIC).	The study population for ZRHCS in Puerto Rico is women of reproductive age, and will include very few pregnant women (estimated to be 2% from previous population-based survey) and focuses on behavioral and prevention data among this group.
Formative Evaluation of Zika Prevention Kits for Pregnant Women in Puerto Rico (0920-1071)	The objective of this information collection is a formative assessment to evaluation Zika Prevention Kits in Puerto Rico. The study population is pregnant women living in Puerto Rico enrolled in the federal supplemental nutrition program for WIC.	The study population for ZRHCS in Puerto Rico is women of reproductive age, and will include very few pregnant women (estimated to be 2% from previous population-based survey) and focuses on behavioral and prevention data among this group.
Case-control GBS study in	The objective of this case-control study is to identify	Not applicable—ZRHCS does not collect information

PR – Surveillance (0920-1106)	potential risk factors for the development of Guillain-Barré syndrome (GBS). The study population is GBS patients who resided in Puerto Rico continuously for the two months prior to onset of GBS.	related to GBS.
Formative evaluation among partners of pregnant women about Zika in PR (0920-0572)	The objective of this formative was to assess possible action for preventing Zika. It does not collect reproductive health related information.	Not applicable – ZRHCS does not propose to evaluate partners of pregnant women.
Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika (0920-1148)	The objective of this information collection is to do a formative/qualitative assessment of contraceptive use in the U.S. Virgin Islands (USVI). The study population is sexually active women (had sex with a man in the last 3 months) in the USVI.	The ZRHCS in Puerto Rico will include women of reproductive age regardless of when or if they last had sex with a man, will cover Puerto Rico versus USVI, and uses quantitative data collection methods.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small business.

6. Consequences of Collecting the Information Less Frequently

This is a one-time follow-up information collection to re-assess various aspects of contraceptive use and other Zika prevention behaviors among women of reproductive age in Puerto Rico one year after an initial survey conducted July-November 2016 (OMB Control No. 0920-1114). Given that Puerto Rico has continued to have more cases than in any other US state or territory, follow up data are needed to assess the effectiveness of emergency response efforts and to make further refinements, including the reach and adherence to prevention messages and information needed for targeting efforts for the Z-CAN contraception access initiative (OMB 0920-170A).

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) A 60-day notice was published in the *Federal Register* on April 27, 2017 Vol. 82, No. 80, pp 19370-19371 to make the public aware of this proposed information collection (**Attachment 2a**). One non-substantive comment was received (**Attachment 2b**).

B) CDC has collaborated internally across the agency with experts in reproductive health, Zika, and sexually transmitted infections. Feedback has been incorporated into the survey from the National Center for Emerging and Zoonotic Infections Diseases; National Center for Health Statistics, Reproductive Statistics Branch (for the National Survey of Family Growth, NSFG); National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health (for BRFSS) and Division of Reproductive Health (for the Pregnancy Risk Assessment Monitoring System, PRAMS, and expertise in contraceptive use measurement). Additionally, CDC has consulted with the Puerto Rico Department of Health including the Puerto Rico BRFSS (PR-BRFSS) unit in developing this survey.

With the exception of Zika-specific questions included in the assessment, all other questions have been drawn from other large surveys, including the NSFG (OMB Control No. 0920-0314), PRAMS, and the BRFSS module on reproductive health, being used in several states (OMB Control No. 0920-1061).

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

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

This survey will be implemented using the data collection infrastructure and methodology established for the Behavioral Risk Factor Surveillance System (BRFSS; OMB Control No. 0920-1061). Previously for the BRFSS, it has been determined that the Privacy Act does not apply. As with the main BRFSS survey, the currently proposed survey will collect information in identifiable form (IIF) such as telephone number and zip code for follow-up purposes. However, the final BRFSS datasets delivered to CDC will not retain any identifying information. Only de-identified data is sent to CDC. Therefore the Privacy Act does not apply. Additional details on the data collection are described in the BRFSS Data User Guide, available at http://www.cdc.gov/brfss/data_documentation/pdf/userguidejune2013.pdf.

Access to data will be limited to CDC contractors and staff who conduct weighting and data cleaning procedures. Security measures for protecting the data will include: 1) Physical controls: CDC facilities are secure, ID accessed buildings. Data will not be stored in hard copy formats; and 2) Technical controls: All electronic data are stored on secured servers protected with firewalls and passwords. All employees are trained on data security measures by taking appropriate Health and Human Services (HHS) courses online. All data collection and records management practices and systems adhere to HHS and CDC IT policies and procedures.

Women aged 18-49 years participating in the main PR-BRFSS survey will be asked if they agree to be contacted once more to answer additional Zika-related questions. Participants will be informed that all information they provide will be kept secure and that they may refuse to participate in the future if they do agree at the time to be called back (**Attachment 3**). Respondents who are re-contacted will be informed again that their participation is purely voluntary, that they may skip or refuse to answer any question, that they will not be asked for any personal information, and that their responses will be kept confidential (**Attachment 4**).

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.

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

IRB Approval

This protocol was submitted for Human Subjects Protection review on February 28, 2017 and received a non-research determination, given that responses will be used to inform Puerto Rico-specific emergency response plans rather than generalizable information (**Attachment 5**).

Justification for Sensitive Questions

Sensitive questions are essential to meeting the goals of this information collection. During the informed consent process, participants will be notified that they may decline to discuss any of the topics or decline to answer any question. Participants will be reminded during the survey that they can refuse to answer any question and still participate in the survey. Because many of the questions to be asked of respondents will deal with sensitive topics, including sexual activity, pregnancy, and contraception, PRDH will be advised to consider using female interviewers.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The estimated burden to respondents is summarized in Table A12.1, below. Eligible participants will be women aged 18-49 years who complete the main PR-BRFSS survey. During October-December 2017, these women will be read a recruitment message once they have completed the main PR-BRFSS survey to ask if they are willing to be re-contacted (**Attachment 3**).

The number of interviews that each jurisdiction completes for the main PR-BRFSS survey is based on the needs, population size and diversity of each jurisdiction. Since May 2017, the PR-BRFSS has completed approximately 215 surveys of women aged 18-49 years each month; based on the expectation that this same number of women will complete the main PR-BRFSS survey each month, during the entire recruitment period for this information collection from May through December, it is anticipated that 1,720 women will be read the recruitment script. However, during the three months of continuing approval from October through December 2017, it is anticipated 645 women will be read the recruitment scrip at an average time burden of 1 minute for a total of 11 burden hours.

The 2016 cooperation rate for the 2016 CAPRZ survey in Puerto Rico (OMB Control #0920-1114) was 96.5%. Therefore, of the 1,720 women who are anticipated to be administered the recruitment script, it is estimated that 1,660 will consent to be called back. Based on experience with the PR-BRFSS Asthma Call-Back Survey in Puerto Rico, it is estimated that of the women who initially consent to be called back, it will be possible to re-contact and complete the callback survey (**Attachment 4**) for 70%, or 1,162 women. However, half of these women are anticipated to be called under the emergency approval period from July through September, so the anticipated number to be called back under the current approval will be 581. The callback survey is largely similar to the 2016 CAPRZ survey in Puerto Rico (OMB Control number 0920-1114), which had an average time burden of 10 minutes. Given this 10 minute time burden, we estimate a total of 97 burden hours for the callback survey.

The burden table also accounts for reporting burden incurred by Puerto Rico for data submission to CDC. Puerto Rico will report information to CDC in the form of a complete, cleaned data file that includes the full set of variables collected for each interview, except that states will first remove identifying information so that the file sent to CDC is de-identified. There is no data collection form that CDC uses for this. For the purpose of this information collection, monthly data submission is assumed over 3 months from October through December 2017 with an estimated 3 hours per response needed for the preparation of the data files for a total of 9 hours.

The total burden hours requested is **117** hours.

Table A.12-1. Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hrs.)	Total Burden Hours
Women aged 18-49 years who completed the main PR-BRFSS survey during May-December 2017	Attachment 3 Recruitment text	645	1	1/60	11
Women aged 18-49 years who completed the main PR-BRFSS survey during May-December 2017 and agree to participate in the call-back survey	Attachment 4 Call-back Survey and Consent	581	1	10/60	97
PR-BRFSS Coordinators	Data Submission Layout	1	3	3	9
Total					117

B. Estimated Annualized Burden Costs

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

Annualized burden costs are summarized in the table below. The hourly wage estimates are based on the Bureau of Labor Statistics May 2015 National Occupational Employment and Wage Estimates (available at http://www.bls.gov/oes/current/oes_nat.htm). The mean hourly wage rate for all occupations (\$23.23) was used.

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Information Collection	Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate	Total Respondent Costs
Women aged 18-49 years who completed the main PR-BRFSS survey during May-December 2017	Attachment 3 Recruitment text	645	11	\$23.23	\$256
Women aged 18-49 years who completed the main PR-BRFSS survey during	Attachment 4 Call-back Survey and Consent	581	97	\$23.23	\$2253

May-December 2017 and agree to participate in the call-back survey					
PR-BRFSS Coordinators	Data Submission Layout	1	9	\$23.23	\$209
Total					\$2,718

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 \$61,742.72. The table below 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 nine months, though with preparation and analysis, the time frame for the project is one year. Hourly wages 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/2017/ATL_h.pdf.

Grade	# of FTEs	Hourly Wage	% time devoted to project	Total Hours	Total
GS-14	1	\$54.37	10	208	\$11,308.96
GS-13	1	\$48.89	10	208	\$10,169.12
GS-12	1	\$38.69	5	104	\$4,023.76
Total					\$25,501.84

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 EOC will take responsibility for all data tabulations for this assessment. CDC's Division of Population Health, which coordinates all Behavioral Risk Factor Surveillance System (BRFSS) activities for the US, will prepare the data files for analysis. This preparation will include final data cleaning and weighting. CDC epidemiologists will perform all data analysis immediately upon availability of final data files. Preliminary data will be analyzed and findings will be shared with Puerto Rico's BRFSS program and the health department. Once final tabulations are available a final report will be published, as well as an MMWR article on key findings.

Project Time Schedule:

- March 29, 2017: CDC staff meets with grantee
- March 30, 2017: Grantee receives funding to implement ZRHCS in Puerto Rico

- April 1- April 15, 2017: Preparations for data collection in Puerto Rico
- May 1-December 15, 2017: Recruitment of eligible women through PR-BRFSS
- July 1 – December 31, 2017: data collection
- September 15, 2017: interim, unweighted data available for analysis
- September 30, 2017: meet with PR-BRFSS unit to discuss interim data
- December 31: end of data collection
- May, 2018: final, weighted data set linked to core PR-BRFSS survey available for analysis
- August 2018: final report and MMWR drafted for ZRHCS

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

The OMB Expiration Date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Public Health Service Act (42 USC 241)
2. (a) 60 Day FRN and (b) Public Comment Received
3. Recruitment Script
4. Call-back Survey and Consent
5. Non-research Determination, Call-back Survey