Assessment of Zika Prevention Strategies in the U.S. Virgin Islands

Request for OMB approval of an Emergency ICR

Supporting Statement A January 23, 2021

Contact: Lee Samuel National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention 1600 Clifton Road, NE Atlanta, Georgia 30333 Phone: (404) 718-1616 Email: llj3@cdc.gov

Table of Contents

1. Circumstances Making the Collection of Information Necessary	2
2. Purpose and Use of the Information Collection	4
3. Use of Improved Information Technology and Burden Reduction	6
4. Efforts to Identify Duplication and Use of Similar Information	6
5. Impact on Small Businesses or Other Small Entities	8
6. Consequences of Collecting the Information Less Frequently	8
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5	8
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency	8
9. Explanation of Any Payment or Gift to Respondents	9
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents	9
11. Institutional Review Board (IRB) and Justification for Sensitive Questions	12
12. Estimates of Annualized Burden Hours and Costs	12
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers	13
14. Annualized Cost to the Government	13
15. Explanation for Program Changes or Adjustments	14
16. Plans for Tabulation and Publication and Project Time Schedule	14
17. Reason(s) Display of OMB Expiration Date is Inappropriate	15
18. Exceptions to Certification for Paperwork Reduction Act Submissions	15
Attachments	15
 A. Authorizing Legislation – Public Health Service Act B. Draft 60-Day FRN C. Interview with Pregnant Women in USVI D. Interview with Community Members in USVI 	
E. IRB Letter of Determination	

F. Explanation of differences between two Zika-related USVI projects

- **Goal:** The overarching goal of this project is to engage key audiences in the U.S. Virgin Islands (USVI) regarding a variety of Zika prevention activities (personal protective behaviors and vector control activities) in order to assess the current situation and to inform future action.
- **Intended use:** Information collected in this assessment will be used to help refine communication and vector control plans and guide implementation of activities defined in those plans in order to prevent and control Zika virus in the U.S. Virgin Islands.
- **Methods:** In-person intercept interviews will be conducted.
- **Subpopulation:** Selected audiences include pregnant women and community members who reside in USVI.
- **Data analysis:** Quantitative data will be analyzed using Epi-Info or SPSS. Qualitative data will be transcribed. The text responses will be uploaded to NVivo, ATLAS ti, or MAXQDA and analyzed for themes.

This is an emergency request for a new information collection for three months. This ICR includes one project, which is part of CDC's ongoing response in USVI to the Zika virus outbreak. Information collection is not expected to exceed three months. In fact, efforts are under way to collect much of this information over a six week period from mid-November to mid-December 2016. However, if it is determined that more than three months is necessary, a formal, non-emergency ICR will be submitted to OMB.

1. Circumstances Making the Collection of Information Necessary

As of October 26, 2016, the U.S. Virgin Islands has reported 1,425 cases of Zika with 575 laboratory-confirmed cases. Sixty-one of these cases are among pregnant women.

Because Zika is an emerging arboviral disease and a sexually transmitted disease that is known to cause microcephaly and other serious birth defects in babies if a pregnant woman is infected during her pregnancy, collaborative response efforts between USVI and CDC are underway.

Specific collaborative activities have included:

- Communications (media relations and educational materials),
- Community and clinical outreach and education,
- Distribution of Zika prevention kits,
- Provision of free Zika testing for pregnant women or people with symptoms, and
- Provision of free vector control services for pregnant women.

Recently, USVI has seen a large jump in cases. Over the first seven months of USVI's Zika response they reported less than 500 reported cases and less than 100 laboratory confirmed cases. In September, they saw a jump in reported cases which has continued climbing exponentially. The chart below shows the reported and laboratory confirmed cases taken from the first weekly surveillance report for each month published on the USVI website (http://doh.vi.gov/topics/az/z/zika.html)

Month	2/16	3/1	4/5	5/3	6/6	7/5	8/2	9/8	10/4	11/2
Reported Zika cases	61	72	148	210	276	349	472	880	1265	1508
Laboratory confirmed positive cases	1	6	13	21	24	32	79	299	462	590

Because several interventions have been offered to pregnant women (e.g., Zika prevention kits, free insecticide services, and communication and education efforts) have been implemented in USVI, it is not clear to response leaders whether intervention delivery is the problem or whether interventions are not having the intended effects. This effort will provide a feedback loop from community members, with an emphasis on pregnant women on these interventions. Response leaders at USVI DOH and CDC have asked the behavioral science team to do a comprehensive assessment of different facets of the response among several audiences in order to help understand the current situation and to inform next steps. Specifically, draft communication plans and vector control plans need to be shaped by a good understanding of several audiences' perspectives on Zika prevention behaviors and vector control activities. The behavioral science team will gather insights from both pregnant women and community members. The insights will support refinement and implementation of the communication and vector control plan. Specifically, incident managers have asked the behavioral science team to:

- Assess pregnant women's knowledge, beliefs, and behaviors pertaining to Zika prevention activities
- Assess community members' knowledge and perceptions of Zika, trusted sources of information, and support for various vector control activities.

This request is for data collection over the next six weeks in USVI. Specifically, USVI's Department of Health and CDC need this assessment to assess the current situation and to inform future actions. Interviews with pregnant women in USVI can help articulate motivations for and against engaging in Zika prevention behaviors that are critical for preventing Zika-associated birth defects and morbidities. Interviews with community members can offer insights about

knowledge, perceive risks, trusted information sources, and perceived barriers and benefits of interventions that could help improve implementation of response efforts.

Concurrently, CDC is also conducting another collection in USVI to explore contraception use among men and women of reproductive age who are not currently pregnant or trying to become pregnant. While the other collection overlaps with this collection in its assessment of knowledge, attitudes, and beliefs the respondent populations are different—the concurrent USVI Zika study carries an emphasis on perceptions and knowledge specific to contraception only, and does not explore other Zika prevention techniques, such as vector control activities, as examined in this study. See attachment F for a detailed breakdown of how these two projects differ.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 USC 241) (Attachment A).

2. Purpose and Use of the Information Collection

The goal of this project is to engage key audiences in USVI regarding a variety of Zika prevention activities in order to assess the current situation and to inform future action.

Objectives

- 1. To describe pregnant women's perceptions of risk, knowledge of Zika protective behaviors, self-reported behaviors, perceived benefits of performing behaviors, barriers and support needed for performing behaviors, receipt of a Zika Prevention Kit, exposure to communications, and trusted sources of information about Zika.
- 2. To describe community members' perceptions of risk, knowledge of Zika, exposure to communications, opinions about select vector control activities, and trusted sources of information about Zika.

Findings will be used to inform implementation of vector control activities and communication efforts for USVI's Zika response. Decisions about vector control are made by local communities, not the federal or state governments. Each jurisdiction has many factors to consider in their decision-making including: the species of mosquitoes present that could be carriers of Zika, the resistance of the mosquitoes to various insecticides, past and present methods for mosquito control (and the presence or absence of a vector control infrastructure), the weather and topography, the types of home dwellings (e.g., screened windows or doors), the sources of water (e.g., ground water or rain water collection via cisterns), local industries (e.g., agriculture, fishing, and tourism), local customs regarding source reduction, previous experiences with vector-borne diseases and outbreaks (e.g., Dengue and Chikungunya), and socioeconomic factors (e.g., poverty). Because Zika risk perceptions influence both personal protective behaviors and community decisions about vector control, local public health

authorities need insights about the perceptions, knowledge, and opinions of key audiences in their communities so that they can make decisions that can be effective in fighting Zika in a way that is also acceptable to the community. In addition, communication channels and trusted sources of information are "local" as well, so questions about channels and sources of information are important for communication to be effective.

This project builds on the work that was done in Puerto Rico by using the same data collection instruments (OMB control no. 0920-1118) as a starting point instead of starting from scratch. These instruments were modified to reflect the USVI context (e.g., permethrin use in USVI is recommended because the mosquitoes that can transmit Zika virus in USVI are not yet resistant to it while in Puerto Rico the species of mosquitoes that transmit Zika virus are resistant to permethrin so it is not recommended there). The vector control strategies recommended for USVI and Puerto Rico are different, so while the method of exploration of acceptability (e.g., focus group discussions) is modeled after collections conducted in Puerto Rico, the actual USVI vector control strategies discussed are different in this collection.

For objective 1, we plan to conduct up to 300 intercept interviews in the waiting rooms of various clinical settings (WIC clinics, maternal and child health clinics, and private OB/GYN offices) across all three islands that make up the USVI. Since most Zika cases are currently on St. Thomas, we will do more interviews there. Targets established by the USVI epidemiologist are as follows: St. Thomas – 150 interviews; St. Croix – 125 interviews; and St. John – 25 interviews). The instrument used for this intercept interview pulls questions from two telephone interviews conducted with pregnant women in Puerto Rico. The domains of the questions are the same but some response options have been modified to reflect the USVI context (e.g., the use of permethrin is a personal protective behavior that is effective in USVI but not in Puerto Rico so it is included in the interview with USVI pregnant women). Interviews with pregnant women will assess the following factors:

- Exposure/experience with receiving interventions targeting pregnant women
- Knowledge about Zika virus and related prevention behaviors
- Self-efficacy in engaging in Zika prevention behaviors
- Engagement in Zika prevention behaviors (e.g., protective clothing use, condom use, and bed net use)
- Knowledge about, attitudes about, and use of the Zika Prevention Kit materials
- Knowledge about, attitudes about, and use of environmental vector control activities
- Risk perceptions of Zika
- Exposures to communications along with other factors that may be important considerations in their taking action or not (e.g., does their house have screens, etc.).

We expect these interviews to take about 20 minutes.

For objective 2, we plan to conduct up to 125 brief intercept interviews in public places on three islands, with most interviews occurring on St. Thomas. Interviews with community members will assess the following factors:

- Knowledge about Zika virus and related prevention behaviors
- Risk perceptions of Zika and knowledge of symptoms
- Actions taken to protect from getting infected with Zika
- Sources of information about Zika and trusted and reliable sources of information
- Types of information desired
- Questions that they have about Zika
- Opinions about several vector control activities

We expect these interviews to take less than 10 minutes.

Results of this project will have limited generalizability. However, results of this assessment should provide information that can be used to shape the planning and implementation of vector control and communication activities in the USVI Zika response effort.

3. Use of Improved Information Technology and Burden Reduction

Interviews will be conducted in the field using Epi Info for Mobile (Android app) running on six Samsung Galaxy Tab A 8.0 devices. Data will be collected into custom forms and sent to CDC over Secure Shell File Transfer Protocol (SFTP). Within the CDC private network, the data will reside in encrypted "eftp" file storage and accessed from CDC network PCs for data processing and analysis. We will use Epi Info for Mobile as our data collection software. Epi Info is a CDC-developed and Section 508 compliant software that will be secured through security services provided by underlying device operating system and hardware. The data collection hardware used will be Samsung Galaxy Tab A 8.0, which are CDC approved devices running the FIPS 140-2 compliant KNOX security platform. Data will be transmitted using a secure shell file transfer protocol (SFTP). We will use SFTP to transmit data into CDC's encrypted private site "eftp.cdc.gov". This site meets the FIPS 140-2 requirements for encryption and is the ITSO recommended path for transmission of Personally Identifiable Information (PII). An Atlantabased data analysis team will review uploaded data for quality and relay any identified issues to the field-based team leader for resolution.

4. Efforts to Identify Duplication and Use of Similar Information

Because of the usefulness of insights gleaned from information collections in Puerto Rico with pregnant women and community leaders that inform Zika response efforts, USVI and CDC are requesting a similar information collection in USVI to inform their response efforts. Instruments from Puerto Rico have been edited to focus on the information that is most needed to shape communication and vector control implementation efforts in USVI.

OMB control	Title	Key differences		
number				
0920-1114	Emergency Zika Package IV: Assessment of Contraceptive Use and Needs, Puerto Rico, 2016	• The primary purpose of this ICR is not to assess contraceptive use among pregnant women and community members in USVI.		
0920-1118	Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections	 Participants are residents of USVI, not Puerto Rico, Participants include pregnant women AND community members in USVI. Community members were not included in the PR information collection. Monthly telephone surveys from a random sample of WIC eligible pregnant women were conducted in Puerto Rico while in USVI a one-time sample of in-person intercept interview is proposed. 		
0920-1126	US-based Migrant Farm Workers Understanding and Use of Measures to Prevent Zika Transmission	Participants are pregnant women and community members in USVI, not migrant farm workers.		
0910-1137	Assessment to Estimate the Effect of Community-Wide Vector Control Initiatives on Zika Virus Transmission in Puerto Rico, 2016	This ICR will not assess the efficacy of vector- control activities.		
0920-XXXX – Undergoing OMB review now	Zika Emergency ICR: Formative Assessment Regarding Contraceptive Use in USVI	Participants are non-pregnant women of reproductive age (See attachment F for a more in- depth discussion.)		
Health Message		requests		
0920-0572	Message testing among important public audiences in Puerto Rico	Conducted brief interviews with various audiences to get feedback on messages. Some are proposed for USVI since there are messages that have been tailored for USVI that have not been tested.		
0920-0572	Formative evaluation of Zika prevention strategies and messages among	tailored for USVI that have not been tested.Conducted focus group discussions with pregnantwomen and community leaders to get theirperspectives on recommended personal protectivebehaviors and proposed vector control actions for		

	pregnant women and community leaders in Puerto Rico	Puerto Rico. These are proposed for USVI to get perspectives of USVI audiences on recently proposed vector control actions.
0920-0572	Message testing	Conducted intercept interviews with male partners
0920-0572	0 0	1 1
	among partners of	to test messages with them
	pregnant women	
Service Delivery	Fast Track Gen IC	
0920-1071	Formative Evaluation	Included intercept interviews with pregnant
	of Zika Prevention	women to get their opinions about the usefulness
	Kits for Pregnant	of Zika Prevention Kits BEFORE they were
	Women in Puerto Rico	implemented as a prevention strategy.
0920-1071	Formative Evaluation	Included focus group discussions with community
	of CDC Autocidal	members in ONE community (Caguas) in Puerto
	Gravid Traps in Puerto	Rico that was exploring being the pilot community
	Rico	for AGO traps

5. Impact on Small Businesses or Other Small Entities

The collection of information does not involve small entities.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection to assess factors that can inform USVI DOH and CDC's response to the public health emergency that increasing cases of Zika represents. Specifically, without this information, USVI DOH and CDC's ability to effectively plan and implement communication and vector control activities in a culturally competent manner may be compromised.

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. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. A 60-day notice was drafted (Attachment B). If it becomes evident that information collection will need to go on for longer than 90 days, a formal, non-emergency ICR will be submitted to OMB. A 60-day notice will be published in the *Federal Register* inviting public comment, followed by a 30-day notice, and OMB review.

B. Leaders in the US Virgin Islands Department of Health's (USVI DOH) incident command structure have been involved in discussions and decisions about this assessment. Specifically, Esther Ellis (epidemiologist) and Monifa Carillo (surveillance officer) reviewed and provided input on the data collection instruments.

9. Explanation of Any Payment or Gift to Respondents.

Because CDC is deploying seven CDC staff to conduct this rapid behavioral assessment in a very short time-frame (six weeks) and a time-frame that includes a major holiday (Thanksgiving), CDC believes incentivizing participation is an important factor in achieving the targeted number of interviews. Recruiting this many participants in a short amount of time will be challenging but can be assisted by the use of incentives in the form of a raffle in which participants completing an interview will have an opportunity to win a cash prize. CDC has proposed two raffles for participants of intercept interviews: one raffle for pregnant women and one raffle for community members.

CDC would like each raffle to have up to three winners and we propose cash prizes, since gift cards do not work at most retail establishments in USVI. Since we do not want names of participants linked to their interview responses, after they complete their interview, the participant will fill out a raffle ticket (with their name and phone number) and put the ticket in container holding other raffle tickets. At the end of our data collection period we will draw prizes for both raffles. For both raffles we propose 3 cash prizes in the following amounts: 1st prize \$50; 2nd prize \$25; and 3rd prize \$25. CDC Foundation funds have been requested for participant incentives.

Recent experiences in conducting evaluations in Puerto Rico(OMB control #0920-1118, Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika Virus Infections)have shown that offering incentives to pregnant women has been extremely helpful in recruiting participants for information collections with very short turn-around times and has conveyed value to participants, who are most vulnerable to the adverse effects of Zika and who feel most threatened by it. Using incentives may improve the survey response rate and will demonstrate respect and appreciation for participants' time and effort. A raffle is feasible to implement and affordable.

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

NCEZID's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply. The only personally identifiable information that will be collected is recordings of respondents' voices. The applicable SORN is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

Impact the proposed collection will have on the respondent's privacy

Prior to participating in the assessment, the interviewer will read prospective respondents their rights as participants, and contacts for more information about the project. Verbal consent from the participant will be requested. Prior to the beginning of the assessment, a staff member will also address any questions the participants have about the project. Participants must provide verbal consent at the time of the interview before any information will be collected.

The assessment has no foreseeable risks other than the very low risk of breach of security. Women are not required to participate. The choice to participate is completely voluntary. Participants have the right to withdraw at any time for any reason. None of the information being collected would reasonably place subjects at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputations. The data collected will be retained for up to one year and then all data will be destroyed.

Final reports, manuscripts, and presentations will contain no information regarding identities of the participants. All collected data will be destroyed within one year after the data collection is complete.

Whether individuals are informed that providing the information is voluntary or mandatory Participation in the assessment is voluntary. Prior to the beginning of the information collection, the interviewer will address any questions the participants have about the project and provide a CDC project email and phone number. Participants must provide verbal consent at the time of the interview before any information will be collected. Interviews will only be conducted with those who agree to participate. Participants will be informed they are free to skip questions they do not wish to answer, respond "I don't know," or end the interview at any time for any reason. Once informed of this information, participant's agreement to participate in the interview will be their consent to participate in the assessment.

Opportunities to consent, and share submission of information

Participation in the assessment is voluntary. Participants must provide verbal consent at the time of the interview before any information will be collected. Interviews will only be conducted with those who agree to participate.

Information secured

Stringent safeguards are in place to ensure a respondent's security including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's and the contractor's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of CDC staff or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. No hard copy records will be created in this information collection.

Interviews will be conducted in the field using Epi Info for Mobile (Android app) running on six Samsung Galaxy Tab A 8.0 devices. Data, which will include audio-recording of the participants responses along with interviewer selected response options on closed-ended questions, will be collected into custom forms and sent to CDC over Secure Shell File Transfer Protocol (SFTP). Within the CDC private network, the data will reside in encrypted "eftp" file storage and accessed from CDC network PCs for data processing and analysis. We will use Epi Info for Mobile as our data collection software. Epi Info is a CDC-developed and Section 508 compliant software that will be secured through security services provided by underlying device operating system and hardware. The data collection hardware used will be Samsung Galaxy Tab A 8.0, which are CDC approved devices running the FIPS 140-2 compliant KNOX security platform. Data will be transmitted using a secure shell file transfer protocol (SFTP). We will use SFTP to transmit data into CDC's encrypted private site "eftp.cdc.gov". This site meets the FIPS 140-2 requirements for encryption and is the ITSO recommended path for transmission of Personally Identifiable Information (PII).

Procedural safeguards: Protections for computerized records include programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily back-up procedures, and secure offsite storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic medical containing Privacy Act information. Finally, CDC employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts and the CDC Project Director, contract officers and project officers oversees compliance with these requirements.

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

Sensitive questions

The interview with pregnant women will ask questions about behaviors related to the sexual transmission of Zika virus (Attachment C). For example, participants will be asked about intercourse and condom use behaviors. To minimize the possibility of distress, participants will be informed that the interview is voluntary, and they are free to skip questions they do not wish to answer, respond "I don't know," or end the interview at any time for any reason. The interview with community members does not ask any sensitive questions (Attachment D).

IRB Approval

This data collection was reviewed by the Scientific Regulations Advisor for the National Center for Emerging and Zoonotic Infectious Diseases and determined to be "public health non-research" (Attachment E).

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on the experience of the team lead in developing comparable interview scripts for a similar assessment projects involving interviews with pregnant women and community members in Puerto Rico. The interview with pregnant women, (Attachment C), including time for reviewing instructions, will take approximately 20 minutes, and the interview with community members (Attachment D) is expected to take less than 10 minutes.

Type of	Form Name	No. of	No. of	Average	Total
Respondent		Respondents	Responses	Burden per	Burden
			per	Response	Hours
			Respondent	_	
Pregnant	Intercept Interview				
woman	with Pregnant women	300	1	20/60	100
	in USVI				
Resident	Intercept Interview				
community	with community	125	1	10/60	21
member	members in USVI				
					121

Table A: Estimated Annualized Burden Hours and Costs

Respondents will be intercepted at settings where they are likely to be found and where they might have time to participate in an interview. To reach pregnant women, interviewers will visit waiting rooms of clinics that have given permission for them to be there. USVI Department of Health will assist in outreach to a variety of clinics serving pregnant women including Women, Infants, and Children (WIC) clinics, maternal and child health clinics (MCH), and clinical offices for Obstetrician and Gynecologists (OB/GYNs) on USVI. To reach community members, USVI will obtain permission for interviewers to conduct interviews in public places on all three islands

that would allow interviewers to intercept people. Settings may include shopping malls, public parks, and government buildings (like libraries) that provide services to community members. Estimates for the average hourly wage for respondents are based on the Bureau of Labor Statistics calculations with data collected from employers in all industry sectors in the U.S. Virgin Islands. The most recent occupational and wage estimates are from May 2015 (http://www.bls.gov/oes/current/oes_vi.htm#00-0000). Based on this data, an average hourly wage of \$16.85 is estimated for all respondents. No data were available on the proportion of pregnant women in the workforce, so we assumed that most of them are in the workforce.

Type of	Form Name	Total Burden	Hourly Wage	Total Respondent
Respondent		Hours	Rate	Costs
Pregnant	Intercept Interview with	100	\$16.85	\$1,685.00
Woman	Pregnant women in USVI	100	\$10.05	\$1,005.00
Resident	Intercept Interview with			
community	community members in	20.83	\$16.85	\$353.85
member	USVI			
				\$2,038.85

Table B. Estimated Annualized Cost to Respondents

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

There will be no costs to the participants other than their time to participate in the interview.

14. Annualized Cost to the Government

There are no equipment costs. The only cost to the federal government would be the travel and salary of the CDC staff supporting the design (protocol and instrument development as well as IRB and OMB approvals), implementation (data collection), and analysis and reporting. The estimated cost to the federal government rates were obtained from the Office of Personnel Management's website (http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/ 2014/general-schedule/) using Atlanta, Georgia localities. Actual salaries may vary by the location and step for each participating employee. The total cost is \$226,472.52. Table 14 describes how this cost estimate was calculated.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Associate Director for Behavioral Science, NCEZID	176	\$76.46	\$13,456.96
Team lead: Primary in assessment design, data	170	\$70.40	ψ13,430.30

Table C: Annualized Cost to the Government

analysis, and outputs.			
Senior Scientist, NCHHSTP			
Deputy team lead: Primary oversight of data collection	240	\$76.46	\$18,350.40
in the field			
3 health scientists			
Primary in training and coaching USVI DOH staff to	528	\$47.95	\$25,317.60
conduct interviews and moderate focus group	520	φ-7.55	Ψ20,017.00
discussions			
1 Data Manager			
Primary in data management and oversight of	176	\$47.95	\$8,439.20
technology used in field data collection			
3 Data analysts 400 \$		\$40.44	\$16,176.00
Primary in data quality control and analysis	400	9 4 0.44	ψ10,170.00
Travel and per diem for 6 CDC staff deployed to USVI			\$74,321.56
to support information collection			$\psi/=,521.00$
Estimated Total Cost of Information Collection			
			\$156,061.72

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

T summary of this unichie is provided below	· •
Project Time Schedule	Timing
OMB approval	By November 7
Data Collection	November 10 – December 16
Data Analysis	Data analysis will begin the week data collection
	occurs, and continue throughout the data collection
	process on a weekly basis
Weekly report of interviews completed in	Weekly throughout data collection period
comparison to targets set	
Data reporting	Preliminary report given as presentation to USVI
	DOH, week of December 12 th
	Preliminary written report given to USVI DOH and
	CDC incident managers week of December 19 th
	Final written report given to USVI DOH and CDC

A summary of this timeline is provided below:

incident managers week of January16th for use in
Zika response planning for calendar year 2017

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

The OMB expiration date will be displayed on the opening screen of the Samsung tablet.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

- A. Authorizing Legislation Public Health Service Act
- B. 60-Day FRN
- C. Interview with Pregnant Women in USVI
- D. Interview with Community Members in USVI
- E. IRB Letter of Determination
- F. Explanation of differences between two Zika-related USVI projects