Communities Organized To Prevent Arboviruses:
An evaluation of an intervention in Ponce, Puerto Rico (COPA)

Request for OMB approval of an Ongoing Information Collection in Use without an OMB Number

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Supporting Statement A

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- **Goal of the study:** To evaluate the acceptability, feasibility, and impact of vector control interventions in in Ponce, Puerto Rico.
- **Intended use of the resulting data:** The data obtained will inform decision making regarding the location, design, and content of future interventions to be implemented and evaluated to reduce the burden of arboviral disease in Puerto Rico.
- **Methods to be used to collect:** Longitudinal follow-up of a community cohort, annual sero-survey, cluster-randomized trial to evaluate the impact of the intervention.
- **The subpopulation to be studied:** All residents, 1 to 50 years old, from 40 selected clusters in Ponce are eligible, we aim to recruit 4,000 participatns.
- **How data will be analyzed:** All statistical analysis will be conducted using SAS Version 9.4 and R Version 3.4.4. Descriptive analysis of all variables will be performed to examine the frequency and distribution of the data.

1. Circumstances Making the Collection of Information Necessary

This information collection request (ICR) is being submitted as an ongoing collection without an OMB number to bring the collection into compliance. We are seeking three years of OMB clearance.

This project was initiated in fall, 2017 by Ponce Health Sciences University (PHSU) in Ponce, Puerto Rico. On May 8, 2018 the COPA project began baseline data collection. As of February 28, 2019, COPA has visited 22,714 selected houses, interviewed and obtained blood specimens for 3,375 participants in 1,962 households and have sent 1,270 laboratory results. Originally, CDC's role was limited to technical assistance including assisting with protocol development, advising on approaches to community-based interventions, vector control activities, diagnostic testing of enrolled patients, and data analysis. Now, CDC's role has evolved to a point where CDC is co-leading this project.

Recent years have seen the emergence of two epidemic arthropod-borne viruses (arboviruses) that are transmitted by Aedes aegypti mosquitoes. Chikungunya virus was introduced into the Caribbean in late 2013, and caused large epidemics of fever with severe joint pain throughout the Caribbean and Americas in 2014. Zika virus was first detected in the Americas in Brazil in 2014, spread throughout the Americas, and has since been associated with devastating birth defects, Guillain-Barre syndrome, and is the first arbovirus that can also be transmitted through sexual contact. In addition, the four viruses that cause dengue were introduced to the Americas over the past several hundred years and have since become endemic, and yellow fever virus has recently caused large outbreaks in Brazil and there is risk of importation to other counties in the Americas.

In all of these cases, the public health response to the spread of these arboviruses throughout the tropics—where their mosquito vectors thrive—has been hampered by a lack of sustainable and effective interventions to prevent infection with any of these arboviruses at the community level. Additionally, the rapid speed with which new arboviruses spread does not often provide the time needed to plan and implement community-level interventions to decrease disease transmission. Although several candidate vaccines for chikungunya and Zika are currently in clinical development,

none are yet available. A dengue vaccine has been licensed in several countries, but initial analyses have suggested that decades will be needed before it results in reduction in transmission of dengue virus.

Among the newer approaches to minimize mosquito-borne transmission of pathogens that cause human disease is the release of mosquitoes infected with a strain of the bacteria Wolbachia. Ae. aegypti is one of the few mosquitoes apparently not naturally infected with Wolbachia, and infection with Wolbachia tends to block transmission of dengue, chikungunya, and Zika viruses. Replacing Ae. aegypti populations with Wolbachia infected mosquitoes is currently being evaluated in large trials against in Southeast Asia and in in Colombia and Brazil. This approach has not been used in the United States. Another approach known as Wolbachia supression, uses Wolbachia to prevent reproduction of mosquitoes by introducing a strain of the bacteria into males that results in sterile eggs from all mating as a result of cytoplasmic incompatibility. The release of large numbers of sterile male insects has been used for agricultural pests with success, such as for screwworm in Central America and tsetse flies in Zanzibar. In the United States, Wolbachia-infected Ae. aegypti mosquitoes can be used under a location-specific Environmental Protection Agency (EPA) Experimental Use Permit (EUP). Field trials of these mosquitoes are underway to provide data to complete EPA's registration process.

A vital part of community-based vector control programs is an investigation of local perceptions of disease and health, disease transmission, the control and prevention of disease, and behavior related to the use of health services. Community perceptions obtained from survey information can then be incorporated into vector control strategies.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

2. Purpose and Use of Information Collection

The aim of this study is to establish longitudinal follow-up of a community cohort in several communities in Southern Puerto Rico and evaluate community acceptance and impact of a novel vector control intervention. The study will evaluate whether the intervention leads to a reduction in *Ae. aegypti* population and a measurable decrease in the incidence of arboviral infection among people in intervention clusters compared to those in non-intervention clusters. The information from this project will be used to inform public health officials about challenges, impact, and acceptability of vector control interventions to better plan and implement such interventions in Puerto Rico. The original plan is to conduct this study for five years, including three years of follow-up once the intervention is implemented. The duration of the project could be expanded depending on support and funding availability.

The general aims of the COPA project are:

AIM 1

Conduct a cluster randomized trial to evaluate the impact of a novel vector control strategy in selected areas in Ponce Puerto Rico.

a. Establish a community cohort to conduct surveillance for arboviral infections in the selected clusters in Ponce, Puerto Rico and follow participants longitudinally.

b. Evaluate the prevalence and annual incidence of arboviral infections in participating areas in Ponce using molecular and serological tests.
c. Evaluate overall health status, mental health, comorbidities, alcohol and drug use, access to health care, knowledge, attitudes, and practices on vector control, and human mobility patterns in the selected clusters.
d. Coordinate the implementation of the intervention with the vector control unit in intervention areas.

AIM 2

Define the clusters selected for participation, and understand local needs to adapt and customize vector control strategies.

a. Evaluate how the cluster is organized and identify community leaders and main stakeholders.
b. Identify main health concerns, health seeking behavior, and health facilities utilized.
c. Describe cluster attitudes and acceptability towards current and novel vector control strategies.
d. Identify the best strategies to get buy-in for proposed vector control strategies from community leaders, stakeholders and community members.
e. Investigate the main barriers and facilitators to implement vector control strategies.
f. Describe what communities consider is their role, the government's role, and other stakeholders' role in mosquito control.

AIM 3

Establish ongoing entomological surveillance for *Ae. aegypti* in selected clusters.

a. Measure mosquito adult populations through the use of autocidal gravid ovitraps (AGO).
b. Conduct an environmental survey to assess potential breeding sites.

AIM 4

To establish a surveillance system to assess annual incidence of acute febrile illness and evaluate its etiology among cohort participants.

a. Evaluate the number of persons with AFI and the number seeking care.
b. Implement participatory surveillance through mobile phone and computer technology.
c. Evaluate the incidence and etiology of non-arboviral acute febrile illness among study participants (separate protocol on banked specimens).

The Puerto Rico Vector Control Unit (PRVCU) was formed as part of a cooperative agreement between the CDC and the Puerto Rico Science, Technology and Research Trust in late 2016. The PRVCU's objectives include establishing surveillance and control of mosquito vectors in Puerto Rico, specifically *Ae. aegypti*. The PRVCU was tasked by the Governor's Executive Order No. OE-2016-037 with overseeing and implementing vector control activities in Puerto Rico in collaboration with other Puerto Rico agencies including the Puerto Rico Health Department and the Puerto Rico Department of Agriculture. The ultimate goal of the program is to impact the *Ae. aegypti* population sufficiently to prevent virus transmission to humans and reduce morbidity and mortality associated with vector-borne diseases.

They are responsible for two components of the COPA project, the implementation of mosquito surveillance and the implementation of the vector control intervention. Since April 1, 2018, PRVCU has been progressively installing autocidal gravid ovitraps (AGOs) for surveillance of adult female *Aedes aegypti* mosquitoes in the 40 clusters. PRVCU has placed traps at a density of 1 trap per 250 square meters across clusters. PRVCU staff carries out mosquito identification counting on a weekly basis.

The selection of the intervention is based on several considerations including: 1) Recommendations from WHO on which intervention is ready for large-scale field trials; 2) EPA regulatory requirements and 3) Community support. In order to determine which intervention to use, the PRVCU conducted consultations with different sectors from the Puerto Rico public and scientific community. The intervention with the highest level of support has been Wolbachia suppression. In support of PRVCU findings, preliminary data from the COPA baseline survey found 70% of participants support the release of non-biting male mosquitoes as an environmentally neutral biological control. We expect this high acceptance level to increase after educational campaigns detailing this vector control strategy. The use of *Wolbachia* to control *Aedes* spp. populations and arboviral disease transmission is regulated by the U.S. Environmental Protection Agency under an Experimental Use Permit. The Puerto Rico Secretary of Health has given preliminary approval for the use of *Wolbachia* suppression. We expect endorsement from the leadership advisory board of the Puerto Rico Vector Control Unit (PRVCU) in early May 2019. Based on the regulatory approvals and community support Wolbachia suppression has been chosen as the intervention. Half of the clusters will receive the intervention and half will serve as controls. The baseline assessment will take two years. Follow-up once the intervention is implemented will be 3 year.

To assess acceptability of traditional and novel vector control interventions, a questionnaire including a brief description of several interventions and the level of opposition/support for each of them will be administered to approximately 50% of adult participants. This information is important to establishing which interventions are more likely to be acceptable to cluster residents. Preliminary results for the baseline were used to inform the selection of the intervention. We wanted to document the level of support and identify areas for additional community education. Participants are asked to explain reason(s) for opposition when applicable, providing valuable information on concerns and misconceptions that can be used to inform future educational campaigns and community activities.

The collection of information will be done through a questionnaire covering demographics, vector control, healthcare seeking behavior and other areas discussed below. The survey incorporated observations from focus group discussions and cognitive testing. The questionnaire will be administered to participants after written consent and verbal assent (when appropriate) has been obtained. Information regarding children aged <7 years will be obtained from one of the parents or legal guardians. At the time of survey administration, ~15 mL of blood will be collected to conduct serologic diagnostic testing for arboviruses.

Specific information collection instruments include:

These questionnaires will be administered to all randomly selected residents, of the selected clusters in Ponce. Being a resident is defined by having slept in the house for at least four of the past seven nights.

Eligibility and consent information (Attachment 3).

Household representative questionnaire (Attachment 4), with general household questions. This questionnaire will be administered to one household representative in each home with one or more participants. This representative should be 21 years or older or an emancipated minor. If all eligible household members are un-emancipated minors, a household member over the age of 50 may act as household representative and complete this section of the survey only. This information is key to ensure follow-up of the cohort, to understand the household composition and contact information. It will also be used to identify sub-groups at higher risk of arboviral infection.

Individual questionnaire (Attachment 4), to be administered to all participants. This section will provide information on past illnesses and health seeking behaviors. It will be used to identify the main healthcare facilities used in the area, and costs associated with acute febrile illness.

Knowledge, attitudes, and practices questionnaire (Attachment 4), to be administered to all participants 7 years and older with questions adapted for ages: 7-11 (younger child), 12-13 (older child), 14-50 (adult). The questionnaire will be focused on vector control. This information will be used to identify factors associated with higher risk of arbovirus infections.

Vector control intervention questionnaire (Attachment 4), to be administered to all participants 21 years or older born on an odd numbered day of the month. This section will be used to assess acceptability of traditional and novel vector control interventions. This information is important to establishing which interventions are more likely to be acceptable to cluster residents. Participants are asked to explain reason(s) for opposition when applicable, providing valuable information on concerns and misconceptions that can be used to inform future educational campaigns and community activities.

Specimen information (Attachment 5). At the time of the questionnaire administration, ~15 mL of blood will be collected to conduct serological testing of arboviruses for a sero-survey. This form is used to identify and track specimens.

Year 2 module (Attachment 6): this module will include household representative questions, demographics, knowledge attitudes and practices, vector control and specimen information similar to year one. It will also include co-morbidities, mental health, drug and alcohol use and a brief mobility assessment. The mobility assessment will be conducted to determine the main places visited by each participant in the past week. Participants will be prompted to recall the locations visited between 6am and 8pm each day, and the time spent at each location, using a tablet-based data collection tool that includes maps. These data will be used to determine the proportion of time spent in intervention and non-intervention clusters and will help explain the level of protection by the intervention.

The sero-survey, individual, and vector control intervention questionnaires will be repeated every 12 months after the initial assessment, up to a period of 5 years. OMB clearance will be extended after three years.

GPS coordinates will also be collected for each household visited to later assess for potential clustering of arboviral infections within neighborhoods. We will ask participants if they have been ill with

arbovirus-like illness (i.e., fever, rash, joint pain, and conjunctivitis) in the past year. If so, we will collect details on the symptoms experienced during their illness.

3. Use of Improved Information Technology and Burden Reduction

Collected data will be directly recorded in tablets to minimize data entry errors and minimize delays in data availability. If paper forms must be used, interview responses will be entered into the database either daily or as a group at the close of data collection Household structure ID numbers and locations will be loaded on to each tablet through an electronic household tracking tool app; structure IDs will also be pre-loaded into EpiInfo for consent and interview information. Questionnaire data will be directly entered into EpiInfo. EpiInfo is a CDC application that allows data entry using electronic devices. In cases where data collection using electronic devices is not possible, the data will be collected on paper. Ten percent of entered forms will be re-checked to identify any problems with data entry accuracy that must be addressed.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of the availability of any similar information. We have communicated with Tom Chapel from the CDC Evaluation office so that they are informed about the project.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

The questionnaires need to be administered annually to be able to provide a comparison of before and after vector control interventions, to detect the impact of an intervention and to increase the robustness of the scientific conclusions of the collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on July 20, 2018, vol. 83, No. 140, pp. 34586-34588 (Attachment 2). CDC did not receive public comments related to this notice.

B. PHSU investigators have extensive experience with the design and implementation of research projects in Ponce, Puerto Rico. CDC staff have worked closely with them to assist with the scientific and technical aspects of the design of the project. PHSU investigators acknowledge the lack of accurate data regarding arboviral disease incidence and prevalence in Puerto Rico, vector control behaviors, on previous collaborations between the two organizations. They have consulted CDC from the beginning of this project to obtain support for the most appropriate approach to obtain; up to date information about arboviral disease incidence and prevalence and vector control behaviors in Puerto Rico.

CDC staff have provided continuous support and advice in the different phases of the protocol development, including statistical calculations and mapping high-risk communities with constant input from PHSU investigators.

PHSU collaborators have provided continuous feedback and valuable advice based on their experience and knowledge of the cultural, geographical, and social conditions of the clusters participating in this project.

PHSU collaborators will continue leading this project, and will be involved in every aspect of the collection and data analysis.

9. Explanation of Any Payment or Gift to Respondents

Participants will be provided with a token of appreciation of 20 dollars, when they accept to provide a blood sample. The token of appreciation is given to the participant even if the blood draw is not successful. For participants under 7 years of age, the parent will receive the full token of appreciation.

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

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply. A Privacy Impact Assessment is included as part of this submission (Attachment 9). The applicable Systems of Records Notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems.

Data collection and management

The COPA data collection and management system utilizes encrypted tablets, EpiInfo and R Shiny software, and encrypted file transport infrastructure and data storage within the CDC network. Data is currently being stored in a secure, limited access CDC network drive, which was implemented to store data containing PII. COPA data collection and management architecture was developed in compliance with federal data security guidelines and CDC's Office of the Chief Information Security Officer (OCISO) policies and tools which have been reviewed and approved for collecting and managing data with PII.OCISO has granted an Authority-To-Develop, a designation to develop the COPA data system in a SQL Server database environment. All DVBD developers will meet OCISO standards in the build-out and deployment of this system. COPA will seek the Authority-To-Operate, an OCISO designation for deployment, once the development of the more complex SQL based system is finalized.

Only interviewers and staff trained in specimen collection will be used in the proposed project. This project will collect and record personal identifying information (e.g., name, contact information, GPS coordinates of residence, picture of the residence). As in all studies involving human subjects, this project will involve people whose rights need to be safeguarded. A sticker with a project identifier will be placed on blood tubes and questionnaires and will be used to link all data collected during the project. All serum specimens will be securely transported to and stored at PHSU/PRI and CDC Dengue Branch labs. All data will be entered into a survey database that will be secure; only personnel on the investigation team will have access to it. All personnel involved in this project will be required to adhere to an unwavering code of conduct regarding the confidentiality of patients' information. Data will be kept as confidential as permitted by law. Hard copies of questionnaires will be stored in a room

at PHSU/PRI that will be locked when not occupied. Based on human subject requirements, paper records will be kept for the duration of the study and at least three years after that. After these period, they will be archived or destroyed according to federal records management guidelines. Access to these files will be limited to project personnel. Electronic copies of the data will be kept in the above-mentioned database, which will be password protected and will only be accessible to relevant project personnel.

Project procedures and confidentiality protection procedures are outlined below:

- A randomly-generated list of numbers will be produced that correspond to households from clusters.
- Households will be visited and offered enrollment. Questionnaires and serum specimens will be collected from participating household members.
- Serum specimens will be received at CDC Dengue Branch and PHSU lab and assigned a numeric identifier that is distinct and unrelated (though traceable) to their identifying information, which will also be entered into the database along with information collected via questionnaires, which will also be entered into a secure database.
- Serum specimens will be tested by RT-PCR and IgM and IgG ELISA for evidence of current, recent, or historic CHIKV, ZIKV, and DENV infection, respectively.
- Test results will be sent to participants by mail or secure email by project staff.
- Data analysis will be performed using the coded, password protected electronic database

Informed consent

The consent form includes authorization to participate in the project, to provide a blood sample, to house inspection, to contact the participants, to send lab results, invite them to informative meetings on vector control and other related topics, and inform them of annual follow-up activities.

We will use the consent summary (Attachment 3) to summarize the most important points of the informed consent to participants.

Consent/assent forms will be generated in English, translated to Spanish by a native Spanish speaker from Puerto Rico, and back-translated to English by a separate person to ensure accuracy. After the participants complete consent and assent if required, project staff will give all patients a simple informational sheet about dengue, chikungunya, and Zika viruses.

Potential participants will also be informed on the consent forms that they should contact PHSU staff should they have any questions about their rights as a research subject.

Data will be stored at Ponce Health Sciences University and CDC's Dengue Branch; only members of the project will have access to the data. Participants' names, addresses and telephone numbers will be collected in case we need to contact them later in the project. This information will be kept secure in password protected computers and locked cabinets. Based on human subject requirements, paper records will be kept for the duration of the study and at least three years after that. After these period, they will be archived or destroyed according to federal records management guidelines.

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

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is research involving human subjects. IRB approval was required (Attachment 7).

CDC's Human Research Protection Office reviewed and approved the request to allow reliance on a non-CDC IRB for protocol #7074, "Communities Organized To Prevent Arborivuses: Assessment of Knowledge, Attitudes, and Vector Control Practices and Sero-Prevalence and Incidence of Arboviral Infection in Ponce, Puerto Rico" in accordance with 45 CFR 46.114. The protocol has been reviewed and approved by the Ponce Medical School Foundation - Ponce Research IRB for the maximum allowable period of twelve months and the IRB's approval will expire on 11/06/2019.

Justification for Sensitive Questions

Sensitive questions will be used to better understand co-morbidities, health-related risk factors, beliefs, and behaviors among study population. These conditions and behaviors have implications for health seeking behavior, arboviral disease outcomes as well as community engagement and education efforts. This study includes a strong component of community engagement to ensure acceptability of the intervention and participation in vector control activities. Understanding other potential health problems will help us tailor community activities and future educational campaigns.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The total number of estimated annualized burden hours for this project is 3,471. Based on preliminary baseline data we estimated the average burden per response.

To meet recruitment goals, the household representative questionnaire will be completed approximately 2,720 times each year. Though the total desired sample is 4,000, we expect the number of household representatives to be 2,720 estimating that we need 86 houses per cluster and one household representative per house. It will take an average of ten minutes to complete each household representative questionnaire for a total annual burden of 454 hours.

The Individual questionnaire will be completed approximately 4,000 times each year, it will take an average of 15 minutes to complete this questionnaire for a total annual burden of 1,000 hours. It will be administered to all participants.

The knowledge, attitudes, and practices questionnaire will be a completed approximately 4,000 times each year. Year one questionnaire will be administered to all participants 7 years and older with questions adapted for ages: 7-11 (younger child), 12-13 (older child), 14-50 (adult), year two follow up questionnaire will be administered to participants 14 years and older. It will take an average of 15 minutes to complete this questionnaire for a total annual burden of 1,000 hours. Number of respondents (4,000) is an overestimation, as there will be some participants under the cutoff age that will not complete this questionnaire.

The vector control intervention questionnaire will be completed approximately 2,100 times, it will take an average of 15 minutes to complete this questionnaire for a total annual burden of 525 hours. It will be administered to all participants 21 years or older, born on an odd numbered day of the month. From preliminary baseline data we estimate that 70% (2,800) of our participants will be between the ages of 21 to 50 and half of them (1,400) will have been born on an odd numbered day of the month.

The specimen collection will be completed approximately 4,000 times each year. Based on preliminary baseline data it will take an average of 10 minutes to complete the specimen collection for a total annual burden of 667 hours. It will be administered to all participants.

The breakdown of how this estimate was reached is in the following table.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Ponce Residents	Household Representative questionnaire	2,720*	1	10/60	454
	Individual questionnaire	4,000	1	15/60	1,000
	Knowledge, Attitudes, and Practices questionnaire	4,000†	1	15/60	1,000
	Vector Control Intervention questionnaire	1,400§	1	15/60	350
	Specimen Collection	4,000	1	10/60	667
Total					3,471

*Houses needed to sample per cluster 68, one household representative per house per cluster

† Overestimated number of respondents, as there will be participants under the cutoff age that will not complete this questionnaire

§ Estimated number of participants with an odd numbered birthday and 21-50 years of age

B. Estimated Annualized Burden Costs

The average annual response burden cost is estimated to be $26,166. The hourly wage estimates are based on the Bureau of Labor Statistics May 2017 National Occupational Employment and Wage Estimates for federal minimum wage. (https://www.dol.gov/general/topic/wages/minimumwage).

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Ponce Residents	COPA Household Representative questionnaire	454	$7.25	$3,292

	COPA Individual questionnaire	1,000	$7.25	$7,250
	COPA Knowledge, Attitudes, and Practices questionnaire	1,000	$7.25	$7,250
	Vector Control Intervention questionnaire	350	$7.25	$2,538
	Specimen Collection	667	$7.25	$4,836
Total				$26,166

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 cost to the federal government is estimated at $1,126,143. The project will require eight Epidemiologists (30% of the time), two Public Health Advisors (80% of the time), three Data Managers (50% of the time), two Fellows full time, one Communication Specialist (30% of the time), two Biostatisticians (20% of the time), two Behavioral Science Specialist (20% of the time), two Programmers (20% of the time), one Data Entry (30% of the time), and 21 Ponce Health Science University employees, including but not limited to, Interviewers, Phlebotomists, and Principal Investigator full time, for one year. For CDC employees, hourly wage rates were used for the Puerto Rico locality. These numbers are available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/RUS_h.aspx. Other CDC contracting employees hourly wages were calculated from the mean national hourly wage for each position this information is available at https://www.bls.gov/oes/current/oes_pr.htm#00-0000. For PHSU employees, the hourly rate is an average of the total amount allocated in the Cooperative Agreement for the institution to hire employees.

Position	Hours	Hourly Wage	Total
Epidemiologist (x8)	624 (x6)	$41.81	$156,536
PHA (x2)	1,664 (x1)	$28.37	$34,415
Fellows (x2)	2,080 (x2)	$28.37	$118,019
Data Managers (x3)	1,040 (x3)	$29.33	$91,510
Communication specialist (x1)	624 (x1)	$26.36	$16.449
Biostatistician (x2)	416 (x2)	$41.81	$34,786
Behavioral Science Specialist (x2)	416 (x2)	$41.81	$34,786
Programmers (x2)	416 (x2)	$23.20	$19,302
Data Entry (x1)	624 (x1)	$13.17	$8,218

PHSU Cooperative Agreement employees (x21)	2,080 (x21)	$14.39	$628,555
Total			$1,126,143

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

Progress reports are generated weekly, monthly and annually to help monitor recruitment and data quality. After the first year of data collection, prevalence rates (as indicated by a positive IgG result to dengue, Zika or chikungunya viruses) will be calculated for each community. With the resulting data, for a future vector control intervention evaluation, clusters could be paired based on prevalence rates; among each pair, with intervention and control status randomly assigned. Annually, the incidence rate in each cluster will be assessed through arboviral disease testing. After completion of the baseline in year 2, we will report on risk factors associated with arbovirus incidence and prevalence, attitudes towards traditional and novel vector control strategies, community attitudes and practices with regards to personal protection methods. Prevalence rates (as indicated by a positive IgG result to dengue, Zika or chikungunya viruses) will be calculated for each cluster. With the resulting data, clusters will be paired based on prevalence rates and human movement frequency; among each pair, with intervention and control status will be randomly assigned. Annually, the incidence rate in each cluster will be assessed through arboviral disease testing. At the end of the 3-year follow up after implementation of the intervention, comparisons will be made between the intervention and control clusters using paired t-tests to assess any difference between groups.

Estimated dates for implementing and completing key activities are demonstrated in the table below.

Timeline for the project communities organized for the prevention of arboviruses.

MILESTONE	FY2018	FY2019	FY2020	FY2021	FY2022
• Complete baseline recruitment*†					
• Lab testing human and vector†§					
• Confirm intervention *†§					
• Obtain EPA permit for Puerto Rico§					
• Broad educational campaign*†§					
• Industry partnership*§					
• Deploy intervention§					
• Cohort follow up*†					
• Continuous AFI surveillance*†					
• Evaluation of intervention impact*†§					

* Will be supported by PHSU
† Will be supported by CDC
§ Will be supported by PRVCU

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. Authorizing Legislation
2. 60-Day FRN
3. Eligibility/Consent

4. Year 1 Module (Household Representative, Individual, Knowledge, Attitudes and Practices, Vector Control intervention questionnaires)
5. Specimen collection form
6. Year 2 Module (Household Representative, Individual/Mobility, Knowledge, Attitudes and Practices, Vector Control intervention questionnaires)
7. IRB Approval Letter
8. Flyer
9. Privacy Impact Assessment