Submission under

0920-1154 Generic Clearance for CDC/ATSDR Formative Research and Tool Development

Expiration: 01/31/2020

**Persuasive Communication about Risks from and Responses to Zika:**

**Focus Groups**

**Supporting Statement Part A**

Version 1

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**Table of Contents**

**Section**

**A. Justification**

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

**Attachments**

Attachment A Authorizing Legislation

Attachment B 60 Day Federal Register Notice

Attachment C Privacy Act Determination Email

Attachment D Focus Group Recruitment Letter

Attachment E Focus Group Consent Script

Attachment F ICRO Exemption Letter

Attachment G Focus Group Zika Vignettes

* Goal of Study (2-3 sentences for each): The goals of this phase of the study to convene demographically diverse public focus groups and use vignettes to deliberate upon emergent controversies such as sex and reproduction and environmental concerns. This activity is part of and will inform future research in a larger, two-year study investigating the sending and receiving components of Zika risk communication efforts. The overall goals of the investigation are to generate recommendations and best practices for how public health professionals might strengthen communication efforts to improve public understanding of, acceptance of, and responses to messaging during both the ongoing Zika virus outbreak and future infectious disease threats.
* Intended use of resulting data: The data gathered during the focus groups will help characterize the risk perceptions, beliefs, values, barriers and social norms that may shape public responses to public health communication regarding Zika. Findings will inform future phases of our research, including a message testing experiment to determine the most effective messages to elicit appropriate public response by soliciting views on beliefs about Zika and barriers to protective action. This effort will also contribute to the development of communication interventions for senior health officials at the state and federal level to be used in the current response and help improve future public health emergency responses. Results will not be generalized beyond the scope of the study.
* Methods: Use a series of qualitative vignettes designed to engage a focus group of individuals (to be identified via outreach to leaders of faith- and community-based organizations in priority locations) in discussions of values, beliefs, and social norms regarding sexual and reproductive decision-making, gender, childbearing, disability, and potentially controversial strategies for vector control (i.e., mass aerial spraying).
* Subpopulation: The eight demographically diverse focus groups will each consist of 7-9 members of the public. Focus groups will be broken down into 4 groups each of women of child-bearing age (18-49) and 4 groups of men and women with equal representation from African-American, Hispanic, and Caucasian population groups.
* Data Analysis: The data obtained from the focus groups will be analyzed using typical qualitative analytic methods to generate common and unique themes.

**A. JUSTIFICATION**

**1. Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC) in collaboration with Johns Hopkins Bloomberg School of Public Health Center for Health Security (CHS), requests eight months of approval from the Office of Management and Budget (OMB) under the generic information collection entitled, “Generic Clearance for CDC/ATSDR Formative Research and Tool Development”, to conduct eight focus groups (roughly three hours each) with demographically diverse members of the public. The purpose of the focus groupsy is to develop a deeper understanding of the social milieu that shapes public responses to both Zika virus and public health messaging around Zika prevention, transmission, and control. The focus groups will engage participants in deeper discussions of these issues by presenting vignettes considering factors that could potentially dissuade women at risk of infection from acting on public health guidance regarding safe sex and pregnancy, as well as perceptions of controversial forms of vector control (i.e., mass aerial spraying).

Zika virus represents a growing infectious disease threat to the US as it expands across the Americas and into the US. A critical study of current public health communication practices for Zika; communication efforts and message delivery via the news media; current knowledge and attitudes about Zika; public values and preferences; and message effectiveness is necessary to understand the effectiveness of current efforts and to improve communication in the future. There is also considerable debate surrounding the appropriate methods of controlling the Zika outbreak and its potential impacts, which may provide insight to potential areas of controversy, such as sex/reproduction, use of new technologies, and environmental concerns, requiring a balancing of values during future outbreaks.1,2,3 While scientific data and judgment are important in these decisions, it is also critical to understand public values and attitudes about risk and about available options. An important opportunity exists to incorporate real-time findings that would be produced by this study, which will result in new data and valuable information to help health officials strengthen communication efforts. Use of the included methodologies has previously advanced the field of risk communication for infectious disease events.4,5,6,7,8,9

The proposed focus groups is a component of a larger, two-year study, *Persuasive Communication about Risks from and Responses to Zika*, examining different aspects of public health communication strategies for Zika and other infectious disease outbreaks. The larger study consists of the following stages:

**Stage 1 Preliminary background research**: Complete an environmental scan of current federal and state communication efforts in place to inform and educate the US public about Zika.

**Stage 2 Review of publically available news articles:** Perform a quantitative content analysis of news media coverage of the Zika outbreak including CDC and public health messages, alternative views, and their representation in the public sphere to determine how the news media has portrayed risks and responses to the public and how that compares to CDC messages.

**Stage 3 Public health interviews**: Conduct in-depth, semi-structured interviews (~45 minutes) with approximately 30 public health practitioners, mosquito control officers, public health policymakers, and public health information officers to develop a detailed understanding of both the standard and innovative communication efforts ongoing in the response to Zika. This portion of the study was conducted as a Generic Information Collection (GenIC) under the CDC/ATSDR Formative Research and Tool Development Generic Clearance Mechanism, (OMB Control No. 0920-1154, Expiration Date 01/31/2020). The title of this OMB approved GenIC was *Persuasive Communication about Risks from and Responses to Zika – State, Local and Tribal Government Interviews*.

**Stage 4 Public survey**: Field an online survey of 800 total people in nine states with higher risk for Zika transmission (CA, AZ, NM, TX, LA, MS, AL, FL, GA). This survey will provide important information to inform future phases of our research by soliciting views on beliefs about Zika and barriers to protective actions.

**Stage 5 Public focus groups**: Convene 8 demographically diverse public focus groups of 7-9 participants each to deliberate relevant issues including emergent controversies such as sex/reproduction, use of new technologies, and environmental concerns, using vignettes to draw out reactions and values important in Zika and future outbreak response. These focus groups will use vignettes informed by earlier phases of the project and illustrate outbreak communication and response efforts in the Zika response and a range of epidemic contexts. Focus groups will take place in a range of locations (New York, Florida, Texas, and Louisiana) that incorporate differences in Zika threat and response, as well as geographic and urban/rural variation. (**Attachment G – Focus Groups**)

**Stage 6 Message Testing**: Conduct a message testing experiment using a nationally representative online sample to test impact of draft statements on audience understanding about the risks they may face and support for public health and personal response activities. Messages will be drafted based on thematic analysis of focus groups and information from the Zika response. This message testing experiment will be completed using the survey research firm GfK Knowledge Networks, and will focus on modified CDC messages, experimental messages informed by previous phases of the project and risk communication best practices, and messages in the news media. CDC plans on submitting this information collection as a GenIC the Health Message Testing Generic Clearance (OMB No. 0920-0572, Expiration date - 3/31/2018).

The ultimate aim of the study is to characterize and provide recommendations for how public health communication practices can be strengthened to improve public understanding of, acceptance of, and response to messages during Zika and future infectious disease outbreaks. As federal, state, and local public health departments conduct activities to educate the public and reduce risks, a greater understanding of the array of communication efforts, messages the public may be receiving via the news media, potential impact of these efforts, and most appropriate ways to communicate about the risks from Zika is needed to inform this and future emergency responses. The ways in which health officials inform and frame their policy positions will determine whether they are able to garner social legitimacy and public trust.

The data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241), included in this request as **Attachment A – Authorizing Legislation**.

**2. Purpose and Use of Information Collection**

This project will provide the CDC with information directly from members of the public, including those living in areas with higher risk for Zika transmission or previously reporting local Zika transmission; this data, in turn, could inform efforts to strengthen and/or troubleshoot ongoing Zika communication efforts and develop communication interventions that may help to improve public response to CDC and public health communications.

This information will help to improve Zika communication efforts with the public and with local partners. In addition, this project will develop evidence-informed recommendations intended to provide strategic input, potential language, and communication approaches for senior health officials at the state and federal level to be used in current and future public health emergency responses. This project aims to advance communication and public health science, improve efforts to deliver effective public health communications, and encourage strong public adoption of public health recommendations. Specifically, this project will enable health officials to: improve communication and messaging interventions to enhance the public understanding of risks; increase public acceptance of public health prevention strategies and interventions during future health threats; and mitigate unnecessary backlash due to poor communication during major health crises.

Analysis of focus group findings comprise Stage 5 in a six-stage project to be completed over two years. These findings will be used to inform the final stage of the project, in which the project team will execute a message testing experiment to characterize the impacts of public health messaging around Zika on public risk perceptions. Information gathered from the focus groups will elucidate public responses to vector control strategies and public health messaging around safe sex and pregnancy by deconstructing the motivations, beliefs, and values underlying those responses.

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CDC will disseminate the information through partners’ online resources, peer reviewed manuscripts, briefings to federal and state officials, and conferences. Interim reports will be shared within CDC to improve the Zika response at the discretion of CDC investigators. All releases of information will be reviewed and approved by CDC. Results will not be generalized beyond the scope of the study.

This project is funded by under a Broad Agency Agreement CDC contract number 200-2016-92378 (09/26/16-09/25/18).

**3. Use of Improved Information Technology and Burden Reduction**

The number of questions and time required for focus groups will be kept to the minimum required in order to elicit the necessary data to inform focus group findings. Earlier phases of this project – environmental scans of state and federal public health communication guidance, a news media content analysis, and qualitative telephone interviews with public health and vector control subject matter experts –informed the content and structure of focus group questions to ensure that appropriate questions are asked of the participants. The focus group discussions will be audio-taped and transcribed, and both the recordings and transcriptions will be stored on a secure server at the project team’s office in Baltimore, MD. Qualitative data analysis software (NVivo) will be used to code the transcripts and extract findings

**4. Efforts to Identify Duplication and Use of Similar Information**

Stage 1 of this study conducted a systematic environmental scan to identify federal, state, territorial and local public health departments’ communication efforts and strategies to understand the content and types of communication strategies and methods being used to disseminate Zika virus information to the public in 2016. This information, however useful, also identified potential gaps in understanding what other standard and innovative communication efforts may be occurring. Additionally, the interviews conducted in Stage 3 of the study generated anecdotal findings (relayed by public health officials, vector control experts, and public information officers) about the general public’s risk perceptions relating to Zika virus. However, members of the public themselves have not yet participated in any part of this study. CDC has already conducted surveys and collected qualitative data on Zika messaging in Puerto Rico and the U.S. Virgin Islands. However, the current effort 1) aims to identify the social norms, beliefs, barriers and values that shape public perceptions of risk and reactions to public health messaging around Zika; 2) investigates how these factors combine to influence behavior; and 3) inform future efforts to develop evidence-based public health messaging interventions around Zika that accounts for the concerns of diverse audiences across the continental United States. Previous efforts have conducted focus groups and distributed questionnaires to elicit public reactions to Zika messaging and campaign materials; assess public understanding of Zika prevention and control; analyze healthcare providers’ perceptions of public health and healthcare preparedness with respect to Zika; and understand community leaders’ efforts in Zika preparedness. This information collection will be unique to previously collections in that it will parse the values and beliefs underlying public attitudes through the use of illustrative vignettes highlighting the ethical and socioeconomic dilemmas associated with Zika infections. This information will help CDC improve communication and messaging interventions to enhance the public understanding of risks; increase public acceptance of public health prevention strategies and interventions during future health threats; and mitigate unnecessary backlash due to poor communication during major health crises.

**5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this data collection.

**6. Consequences of Collecting the Information Less Frequently**

This request is for a one-time information collection. Neglecting to collect updated information from diverse members of the public will limit our understanding of the full range of social, economic, historical, and political factors shaping public risk perception, attitudes regarding potentially controversial dimensions of Zika virus infection and prevention (i.e. contraception and mass aerial spraying), and responses to public health messaging around Zika. Soliciting this information directly from members of the public via focus groups will enable us to develop a nuanced understanding of the aforementioned issues, in a way that analyses of existing scholarship and gray literature will not. Furthermore, the beliefs and barriers may shift over time as competing issues vie for the public’s attention and the outbreak evolves so updated information is necessary to ensure that current messaging targets are appropriate and accurate. Obtaining feedback directly from the public will also more effectively facilitate development of effective public health messaging interventions around Zika and future infectious disease threats. There are no legal obstacles to reducing the burden.

**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 Agencies**

The Federal Register notice was published for this collection on July 18, 2016, Vol. 81, No. 137, pp. 46680 (**Attachment B**). No public comments were received.

No other public contacts and opportunities for public comments were received.

**9. Explanation of Any Payment or Gift to Respondents**

Focus group participants will be provided $75 as a token of appreciation for their three-hour participation in face-to-face focus groups. This token of appreciation will account for travel to, and participation in, a 3 hour face to face focus group, for which dependent or child care arrangements may need to be secured or expenses for travel may be incurred such as parking or public transportation. These challenges can present a significant burden to participants. Numerous empirical studies indicate honoraria significantly increase response rates. 10, 11, 12 The token of appreciation amounts for focus group participants were determined through discussions with CHS and CDC staff with expertise in conducting focus groups, about health topics with similar consumer populations in the US.

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

This submission has been reviewed by the OPHPR Paperwork Reduction Act contact and it has been determined that the Privacy Act does not apply **(Attachment C).** No CDC staff will participate in the collection of data or otherwise have contact with the participants.

To enable focus group participation, the following information in the Identifiable Information Form will be used: names, email addresses, and telephone numbers. However, CHS will not be linking any portion of focus group transcripts or recordings with this personal information.

The collection should have no impact on privacy. Personally identifiable information will not be recorded in the data. Data will be coded and aggregated, so it will not be possible to link responses with any individual subjects. Respondent comments will not be attributed to specific individuals. Written notes and focus group recordings will be labeled and stored under generic descriptive names, and results will only be available to the CHS project team via secured access. Furthermore, study reports will not name specific participants or organizations without their explicit permission.

The information will be treated as private, de-identified, and stored securely at CHS. Electronic data will be stored at CHS on secure, password-protected servers with random alphanumeric codes assigned as file names. Hard copy data will be stored under lock and key. The data will be shared securely with study investigators without revealing participants’ names, email addresses, or other personal identifiers. The recording device containing focus group audio files will be stored under lock and key until the files are transferred to the secure electronic server at CHS. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

Participants will be informed that providing information is voluntary as shown in **Attachment D** and **Attachment E**. Participants will be given an opportunity to consent to sharing and submitting information as shown in **Attachment D** and **Attachment E**.

A system of records is not being created for this study.

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

IRB Approval

The study has been determined to be exempt from IRB **(Attachment F)**.

Sensitive Questions

Some of the questions posed to participants in the focus groups – specifically, those pertaining to safe sex, contraception, pregnancy, and personal beliefs – may be of a sensitive nature. However, collecting this information is critical to developing a comprehensive understanding of the social milieu shaping public responses to Zika messaging. The investigators will not ask focus group participants to describe their personal experiences engaging with these issues; rather, participants will be asked instead for their opinions based on a fictional scenario about a friend’s experience. None of the information shared in the focus groups will be attributed to individual participants. The investigators will use this information to clarify how and why certain messages regarding Zika prevention and control are well-received, while others might elicit undesired responses from intended audiences. These data, in turn, will inform the next phase of the project, in which the investigators will design and test different public health messages regarding Zika. Explanation for the use of the information will be provided and consent obtained at the beginning of each focus group.

**12. Estimates of Annualized Burden Hours and Costs**

The annualized response burden is estimated at 216 hours.

Eight focus groups, each consisting of 7-9 members of the public will be recruited by conducting outreach to leaders of faith-based and community-based organizations identified from publicly available lists of local community groups, or as recommended by health departments.

**Exhibit 12.A Annualized Burden Hours**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Number of Respondents** | **Number of Responses per Respondent** | **Average Burden per Response (in hours)** | **Total Burden Hours** |
| Individuals | **Attachment G - Focus Group Vignettes** | 72 | 1 | 3 | 216 |
| Total |  |  |  |  | 216 |

**12.B Estimated Annualized Costs**

The United States Department of Labor, Bureau of Labor Statistics May 2015 data were used to estimate the median hourly wage of all populations since our study is collecting data from the public and not specifying any particular profession (<https://www.bls.gov/oes/current/oes_nat.htm#00-0000>).

Exhibit 12.B. Annualized Cost to Respondents

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Cost** |
| Individuals | **Attachment G –**  **Focus Group Vignettes** | 216 | $17.81 | $3,846.96 |
| Total |  |  |  | $3,846.96 |

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

There are no other cost burdens to respondents and record keepers for this data collection.

**14. Annualized Costs to the Government**

No CDC staff will be involved in recruitment of respondents or any data collection. The annual total cost of data collection by the CHS contractor for the focus group portion of the study is $229,655.00.

**15. Explanation for Program Changes or Adjustments**

This is a new generic information collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Exhibit 3 illustrates the timeline for activities related to this collection, including recruitment of participants, data collection, data analysis, and publication.

**Exhibit 3. Focus Group Timeline**

|  |  |
| --- | --- |
| **Activity** | **Time Schedule** |
| Recruitment | Focus Groups: 2 months after OMB approval |
| Data Collection | Focus Groups: 4 months after OMB approval |
| Data Analysis | Focus Groups: 6 months after OMB approval |
| Report Results | Focus Groups: 7 months after OMB approval |

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

The display of the OMB expiration date is not inappropriate.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

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