Information Collection Request:
Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika

Request for OMB approval of an Emergency ICR

January 23, 2021

Supporting Statement B

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B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

This request is for a project to conduct of a series of focus groups with women of reproductive age (WRA; 18-44 years) and men of reproductive age (MRA; 18-44 years) in the U.S. Virgin Islands (USVI) to explore current knowledge, attitudes, and beliefs regarding contraception use, in general, and related to Zika virus exposure, in particular. Qualitative methods, such as focus groups, provide flexible in-depth exploration of the participants' perceptions and experience; and the interviews yield descriptions in the participants' own words. Qualitative methods also allow the interviewer flexibility to pursue relevant and important issues as they arise during the discussion. Our discussion guides (exploratory, concept, messages and materials testing) include probes to ensure that we obtain input on specific items of interest, while open-ended questions ensure that participants' responses and perceptions are fully addressed and captured **(Attachment B** and **Attachment C).**

Our sample will be a non-probability based purposive sample; therefore, the results will not be generalizable to the general population. However, to enhance representation, recruitment activities will be conducted across the major islands of the USVI (i.e., St. Thomas, St. Croix, and St. John), and focus groups will be held at different community-based sites across the islands to increase participations rates. While the focus groups are for the purpose of tailoring messages and materials to the larger population, there is no statistical power to generalize. No more than 72 individuals will participate in the focus groups, resulting in 6 groups, each with no more than 12 individuals. Four to five groups will be with WRA, whereas one group will be with MRA.

2. Procedures for the Collection of Information

All information will be requested through conversational focus groups. Women's groups will be stratified by age (18-24 years vs. 25-44 years). These age divisions are designed to facilitate easier and more focused conversation with the idea that younger women and older women may have some differences in their attitudes, behaviors, knowledge and beliefs, and be more comfortable talking with peers. Men's groups will consist of those aged 18-44 years; there will be no stratification.

Recruitment for participation will be conducted by staff of the USVI Department of Health (DOH) and local community-based organizations (CBOs) who will also work with CDC headquarters staff to handle logistics of running the groups, including providing a location for the groups that is convenient and accessible to the community. CDC staff will facilitate the focus groups. Recruitment of participants will be done with a screener via phone with referrals from community-based organizations and health centers (Attachment F). Alternatively, recruitment and eligibility screening may also occur via in-person intercepts at health department/health center locations and community-based organizations, or venues where the target population may congregate (e.g., nail and hair salons; grocery stores).

We propose to conduct 4-6 focus groups. One group will be conducted among men ages 18-44, and 4-5 groups will be conducted with women of reproductive age (18-44 years). The women's focus groups will be stratified by age (18-24 years vs. 25-44 years). These focus groups will be exploratory in nature, providing information on contraceptive use and access in the USVI to inform the development of culturally-appropriate messaging.

No personal identifying information, such as names, addresses, or phone numbers, will be collected during the focus groups or maintained in any data files. All individuals involved in data collection shall be trained concerning procedures and practices to ensure privacy of data and will be required to undergo ethics and protection of human subjects training through an accredited course (e.g., CITI). Identifying information collected over the course of recruitment on the screeners will be maintained at the facilities of either the local CBOs or the USVI DOH that solicited participation for the purpose of sending reminder emails or making reminder phone calls. The screeners will be kept in locked file cabinets and/or secure servers. Once the project ends, the screeners will be destroyed. Reminder calls/e-mails for the focus groups will be conducted with potential participants approximately 1 to two days prior to the data collection to provide directions to the focus group site and confirm participation.

Once the potential participant arrives at the focus group site and checks in s/he will be given a consent form **(Attachment D)**. The individual will be given time to read the consent form on his/her own and a trained facilitator will be available to answer any questions. All participants will be reminded that they can refuse to answer any question and they can stop being in the study at any time, without penalty. The participant will be given a copy of the consent form to keep for her/his records, and we will proceed with the data collection. The consent forms will be stored in a locked file cabinet for the duration of the project. Once the project ends, all forms will be destroyed.

Each focus group will last a maximum of 2 hours. Focus group discussion guides consist of a series of open-ended questions and probes for the facilitator in order to generate conversation among the participants **(Attachment B** and **Attachment C)**. The questions will be reviewed by local partners and modified when necessary to incorporate cultural context and to appropriately reflect the anticipated education level of participants. The focus groups will take place in a private setting and will be conducted in English. Each focus group will be facilitated by an experienced moderator. Another staff person will attend the data collection to take notes on a laptop computer and to coordinate logistics of checking in participants and obtaining informed consent. All focus groups will be audio-recorded and notes will be taken in order to capture non-verbal or inaudible responses. All audio-recordings will be destroyed after notes have been verified and no links will be maintained to any data collected.

At the conclusion of the focus group, we will ask for them to initial a receipt form for their token of appreciation. The receipt form is for accounting purposes only and requires that the participant provide her/his initials.

3. Methods to Maximize Response Rates and Deal with No Response

The following procedures will be used to maximize cooperation and to achieve the desired participation rates in our focus groups:

- Recruitment/screening through community partners;
- Recruitment/screening at venues where the general public tends to gather;
- Reminder calls/e-mails with directions to the focus group site 1 to 2 days prior to the scheduled data collection; and
- Provision of a token of appreciation to thank participants for their time and effort in the study.

Additionally, facilitators will encourage all focus group participants to engage and contribute to the discussion.

4. Tests of Procedures or Methods to Be Undertaken

Given the study design, no testing procedures are require. The focus group guides were developed using open-ended items that have been previously utilized in similar studies. Furthermore, community-based partners have reviewed the guides to address relevance and appropriateness to the target audience.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting or Analyzing Data

Members of the CDC study team were consulted in the development of the methodological approach, including the data analysis, for this information collection request. Due to the qualitative nature of this study, no statistical techniques will be employed. However, a robust analytic approach will be applied, including the use of two independent coders and the assessment of inter-rater reliability. An *a priori* code book will be established based on the focus group guides developed for the study. However, the code book will be modified to address any emergent codes that are identified during the coding process. The resulting thematic analysis will determine common themes related to the overarching study domains. Prior to data collection, the focus group instruments were reviewed by local partners who will also be actively engaged in the recruitment/screening processes.