Generic Clearance for CDC/ATSDR
Formative Research and Tool Development

OMB #0920-1154

Supporting Statement A

The Zika Family Survey: In-depth Interviews with Women Affected by Zika Virus

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A. Justification

Attachments

- **Goals of the study:** To assess the kinds of healthcare and support services that women who were exposed to Zika virus during pregnancy are receiving, and to identify challenges these mothers may encounter in receiving appropriate services for their infant.

- **Intended use of the resulting data:** To identify the types of services that Zika-affected pregnant women and children need and ultimately work with national, regional, and local partner organizations to fulfill those needs. The results will inform ongoing and future activities between CDC and March of Dimes to support families affected by Zika, and will not be generalizable.

- **Methods to be used to collect data:** In-depth interviews via telephone.

- **The subpopulation to be studied:** Women residing in the states of Virginia or Pennsylvania who are included in the US Zika Pregnancy and Infant Registry and delivered a live birth.

- **How data will be analyzed:** Descriptive analyses and thematic or grounded theory analysis of qualitative data.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a one-year Office of Management and Budget (OMB) approval for a new genIC entitled "The Zika Family Survey: In-depth Interviews with Women Affected by Zika Virus." The goals of this study are to assess the kinds of healthcare and support services that women who were exposed to Zika virus during pregnancy are receiving, and to identify challenges these mothers may encounter in receiving appropriate services for their infant.

In collaboration with state, tribal, local, and territorial health departments, CDC established the US Zika Pregnancy and Infant Registry (USZPIR) in early 2016 to monitor pregnant women with laboratory evidence of possible recent Zika virus infection and their infants. Zika virus infection during pregnancy can lead to conditions in the baby called congenital Zika syndrome (https://www.cdc.gov/zika/healtheffects/birth_defects.html). A baby with congenital Zika syndrome might have one or more of the following conditions: microcephaly, problems with brain development, feeding problems, hearing loss, seizures, and vision problems. Babies affected by Zika virus infection may have lasting special needs. Some of the conditions listed above can lead to problems with a child's progress in moving, learning, speaking, and playing, called developmental delay. These babies may need additional exams and tests from various healthcare specialists. There currently are services, like early intervention, that can help babies and support programs for parents. Little is known about whether parents seek out and receive these services for their infants.

In 2017, CDC updated its interim guidance for US health care providers caring for infants born to mothers with possible Zika virus infection during pregnancy (Adebanjo T, et al, 2017). A recent study by CDC found that providers were not following the recommended guidelines for providing healthcare to pregnant women who tested positive for Zika and their babies (Reynolds et al., 2017). Not evaluating these babies could lead to missed diagnoses and possibly a delay in the recognition and treatment of cognitive development delays, hearing abnormalities, and visual disturbances seen in babies born with Zika. Additionally, the availability of services is variable throughout the United States. The degree to which providers and community organizations promote services to parents of infants who are affected with the Zika virus is unknown. Research is needed to understand the barriers that parents with infants affected by Zika perceive and face. This

study will interview women who are in the US Zika Pregnancy and Infant Registry to better understand their knowledge of the healthcare and support services their infants should be receiving and barriers they face in trying to access these services.

The CDC has awarded funding to the March of Dimes Foundation, who has subcontracted with RTI International (RTI), to support Zika Response Project activities, which includes collecting qualitative data from women who were exposed to Zika virus during pregnancy and to identify challenges these mothers may encounter in receiving appropriate services for their infant.

2. Purpose and Use of Information Collection

The purpose of this study is to conduct formative research to assess the kinds of healthcare and support services that women who were exposed to Zika virus during pregnancy are receiving, and to identify challenges these mothers may encounter in receiving appropriate services for their infant. The research results will be used to identify the types of services that Zika-affected pregnant women and children need and work with national, regional, and local partner organizations to fulfill these needs.

RTI will conduct all data collection related to the proposed study and will work collaboratively with the state health departments in Virginia and Pennsylvania. Data collection will consist of in-depth interviews with women who are part of the US Zika Pregnancy and Infant Registry. Through the in-depth interviews, the following issues will be examined: the mother's initial information needs; transition from prenatal care; the infant's healthcare, early intervention and other support services; and social support and family services.

3. Use of Improved Information Technology and Burden Reduction

This study will consist of data collection through the use of one-time interviews conducted via telephone. Where possible and upon consent from the participant, the contractor will audio-record the data collection to capture all information and help prepare reports.

4. Efforts to Identify Duplication and Use of Similar Information

Because of the emergent nature of the Zika virus in the United States, there is no available literature on this issue. CDC has partnered with the March of Dimes, a non-governmental leader in supporting families affected by Zika. Neither CDC nor March of Dimes is aware of similar studies.

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 is an ad hoc data collection (i.e., a one-time study to gather information from women who have been affected by Zika and does not require periodic collection of data). There are no legal obstacles to reduce burden. The present study will provide the primary data needed to address the goals of this study. If this formative research was not conducted, information needed to inform the needs of mothers with an infant affected by Zika would not be gathered.

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

CDC project staff collaborated with RTI and March of Dimes on the study design, recruitment materials, and data collection instruments. RTI staff are trained and experienced in conducting formative research on emerging infections in pregnancy and other sensitive topics. CDC recognizes the importance of gaining valuable insights from experts who have content expertise and experience working with this audience. Individuals consulted with and their roles are listed in **Exhibit A.8.1**. No major problems were identified that could not be resolved.

Exhibit A.8.1. CDC Project Staff and Other Consultants

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9. Explanation of Any Payment or Gift to Respondents

The in-depth interviews will take approximately one hour to complete. Participants will be offered a token of appreciation of $40 in the form of a VISA check card. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). The token of appreciation amounts were determined through discussions with contract staff with expertise in conducting interviews with the study population and interviews about other sensitive topics. Removing the incentive would incur significant costs and timeline delays, which could threaten the development of a strategy to provide better services to pregnant women and children impacted by Zika. Also, incentives will ensure participation from hard-to-reach populations critical for this study.

All participants will also receive $2.00 in cash included with the introductory letter (**Attachment A**), which will offset any personal telephone data use charges for participating in the interviews. There is substantial evidence that pre-paid incentives are effective at increasing response rates and reducing recruitment costs (Beckler & Ott, 2007, Edwards, et al, 2002, Church, et al, 1993,). A study by Cantor, O'Hare, and O'Connor (2008) showed that prepayment of $1 to $5 increased response rates from 2-12 percentage points versus offering no prepaid incentive, and can result in lower costs related to follow-up. Offering the pre-paid incentive may also help prevent biases introduced by lower participation rates among the economically disadvantaged participants if they do not have enough mobile minutes to participate in the interview.

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

The CDC Privacy Office has reviewed the collection and has determined that the Privacy Act does not apply.

Recruitment and data collection instruments for the study are provided in **Attachments A** through **E**. Before data collection, the interviewer will verbally review the consent form in plain language to account for participants with lower literacy (**Attachment D)** and participants will be given time to ask questions. Upon verbal consent, the interviewer will proceed with the interview.

The moderator will use plain language to review key parts of the informed consent, which will include informing participants of the following:

1. The interview is voluntary; participants may choose not to answer any question and can end participation at any time.

2. The contractor will report findings in summary form so that participants cannot be identified and that their identifiable information will be kept secure and separate from the interview notes and audio recordings.
3. All individuals on the call, including note-takers and potential staff observers, will identify themselves before the interview begins.

We have put in place several provisions to protect the privacy of respondents. First, RTI will work with the Zika Pregnancy and Infant Registry staff at two state health departments: Virginia and Pennsylvania. Only the Registry staff will have the contact information for women in the USZPIR. RTI will not have access to that contact information until women elect to contact them if interested in participating, or allow the health department to share their contact information with RTI. When RTI receives respondent contact information, all personal information will be stored on a secured share drive. Participants will receive a subject ID that is not associated with any personal identifiers, and participant responses will not be attached to any personal identifiers, only to the subject ID. RTI will report findings in a summary report. CDC will not receive any personally identifiable information (PII),

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

IRB Approval

This project has received IRB approval through RTI International's IRB. IRB approval was granted on 02/15/2018 and will expire on 02/15/2019. The current IRB approval letter is included as **Attachment F**.

In the course of conducting this research, all respondents will be assured that they may skip any question if it makes them uncomfortable and end the interview at any time. They will also be told the information will be used only for the purpose of this research and will be kept secure to the extent allowable by law, as detailed in the consent forms (see **Attachment D**). Respondents will be assured that their responses shared during the in-depth interviews will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Respondents will be told that the information obtained will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only.

The study asks some questions of a sensitive nature, including questions about whether the participant's child has been diagnosed with health issues related to Zika. This measurement of sensitive questions is necessary to thoroughly assess what services have been provided to the infant, and whether gaps exist related to treatment and other service provision. The interviewers are will be trained to ask these questions in the most sensitive way possible, gauge reactions, and remind the respondents that they may skip any questions they find uncomfortable.

A.12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 125 hours.

Exhibits A.12.A and **A.12.B** provide details about how this estimate was calculated. The registries have indicated there are likely 100 individuals who meet the study criteria. RTI anticipates a response rate of 60%, thereby conducting interviews with up to 60 individuals. Recruitment will take up to 15 minutes. The interviews will take up to 60 minutes to conduct. **Total burden hours are 85.**

Exhibit A.12.A Annualized Burden Hours

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours*
Women enrolled in the U.S. Zika Pregnancy Registry	***Recruitment***				
	Introductory Letter	100	1	5/60	8
	Follow-up Call from State Registry	100	1	10/60	17
	In-depth interviews				
	Interview Guide	60	1	60/60	60
	Totals				**85**

**Rounded to the nearest hour.*

Exhibit A.12.B. Annualized Cost to Respondents

Respondents	No. of	No. of	Average	Hourly	Total	Total

	Respondents	Responses per Respondent	Burden per Response (in Hours)	Wage Rate	Burden Hours*	Respondent Costs**
Women enrolled in the U.S. Zika Pregnancy Registry - contacted	100	1	15/60	$23.23	25	$580.75
Women enrolled in the U.S. Zika Pregnancy Registry - contacted	60	1	60/60	$23.23	60	$1393.80
					Total	**$1,974.55**

**Rounded to the nearest hour.*
***Rounded to the nearest dollar.*

The United States Department of Labor, Bureau of Labor Statistics May,2015 http://www.bls.gov/oes/current/oes291069.htm.) data were used to estimate the hourly wage rate for the general public and for private providers for the purpose of this generic request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of $20.00 per hour was used as an estimate of average hourly wage across the country.

Because the wage rate category for selected participants (or even whether they will be employed at all) is unknown, $23.23 per hour was selected as this is an estimate of mean hourly wage for all occupations across the country (Bureau of Labor Statistics, 2016). The estimated annual cost burden to participants for information collection will be $2,903.75.

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

There are no other costs to respondents or record keepers.

A.14. Annualized Costs to the Government

The average annualized cost to the federal government to collect this information is $250,450.00. The federal government personnel estimate is based on cost of the three CDC staff and two consultants. Federal staff and consultant responsibilities include overall management and oversight of the project and provision of content matter expertise in the development of the research strategy and data collection instruments. Contractor costs include direct labor for

development of instruments, data collection, analysis and reporting for both phases of the formative research. Other direct contractor costs include subcontractors, travel, and facility rental, participant recruitment and incentives; and indirect costs such as fringe, overhead, general and administrative fees (**Exhibit A.14.1**)

Exhibit A.14.1. Government Costs

		Percent Time	Total ($)
Federal Government Personnel Costs	CDC Behavioral Scientist/Technical Monitor (GS-11)	10%	$12,522
	CDC Behavioral Scientist (GS-13)	5%	$5,004
	CDC Health Scientist (GS-15)	5%	$6,956
Total Contractor Costs	Personnel, fringe, overhead, general and administrative fees	n/a	$220,568
Total Annualized Cost to Government			$250,450

A.15. Explanation for Program Changes or Adjustments

No change in burden is requested as this is a new information collection.

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

Data from the in-depth interviews will be transcribed by the contractor during the data collection process and stored on a password-protected computer. RTI will conduct thematic or ground theory analysis of the data to understand participants' reactions to the interview questions in a rigorous and detailed manner. RTI analysts will analyze the data and produce a written report describing the major findings from the in-depth interviews. The key events and reports to be prepared are listed in **Exhibit A.16.1**.

Exhibit A.16.1. Project Activities and Time Schedule

Activity	Time Schedule
Begin Recruitment	1 month after OMB approval
Conduct Interviews	2 months after OMB approval
Transcribe Interviews and De-identify Data	3 months after OMB approval
Analyze Data	3 months after OMB approval
Draft report due	4 months after OMB approval
Final report due	4 months after OMB approval

Research findings will be disseminated to a number of audiences. The main reporting and dissemination mechanism will be in the form of a final research report. The final report will be written in clear language that is understandable by a wide range of audiences (i.e. state health departments, policy makers, and researchers). The final report will include the following information: an executive summary, overview of background literature to provide contextual information about the purpose of the research, a detailed summary of the research methods and results, a discussion of findings, strengths and limitations of the research, and future directions for services for women and their babies affected by Zika.

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

The display of the OMB expiration date is not inappropriate.

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

There are no exceptions to the certification.

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