GenIC Clearance for CDC/ATSDR

Formative Research and Tool Development

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Supporting Statement B

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

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The study sample is limited to women who are included in the US Zika Pregnancy and Infant Registry (USZPIR), reside in Virginia or Pennsylvania, and have had a live birth. We anticipate that there will be approximately 100 women in these two state registries that would meet our study criteria. Specifically, women are eligible if

1. They had been pregnant and had laboratory evidence of Zika virus infection (positive or equivocal Zika virus test result, regardless of whether they have symptoms), or
2. They gave birth to an infant with laboratory evidence of congenital Zika virus infection (positive Zika virus test result or equivocal test result if the infant has symptoms consistent with Zika infection).

B2. Procedures for the Collection of Information

RTI will work with the state registries in Virginia and Pennsylvania to identify all eligible women. The Registries in both states will contact eligible women about the study, following the steps described below. RTI will develop the recruitment materials (English and Spanish) for use by the Registries.

Step 1. Registries Send Letters to Eligible Women

The Registries in Virginia and Pennsylvania will send letters to eligible women to inform them about the study and provide instructions for contacting RTI about participation. The letter will include several options for women to reply: by telephone, email, return postcard, or on a study website (see Step 4). Each letter will include $2.00 to cover any costs associated with telephone costs for the interview (e.g., prepaid minutes) on the part of the participant. The Registries will send the letters via priority mail, which generally results in higher response rates. The letter is included in **Attachment A**.

Step 2. Option: Registries Follow-up with Eligible Women by Phone

Registries will contact women by phone approximately one week after sending the letters. The purpose of the call is to confirm that women received the letter, review the purpose of the study, address any questions or concerns, and explain how they can participate. Registry

staff will make 3 attempts to contact women. After the third attempt, they will leave a generic message for the woman to contact the health department (see Appendix A).

The registries could also obtain verbal consent from women to provide their contact information to RTI. The registries would provide names and contact information for women who have consented, and RTI would contact them to schedule an interview. The script for the follow-up calls and FAQs to address potential questions and concerns is included in **Attachment C.**

Step 3. Registries Inform Pediatricians About the Study

The registries will send letters to pediatricians who provide care to the babies of eligible women to inform them about the study. The letter will provide information about the purpose of the study and advise that one or more mothers of babies in their practice have been invited to participate. The letter will include contact information for the state registries in case pediatricians have any concerns or questions about the study (**Attachment B).**

Step 4. Women Contact RTI about Participation

Women who are potentially interested in participating in the study can contact RTI directly by return postcard, telephone, email, or on a study website. All methods of communication will be available in English and Spanish.

- **Postcard:** Women can send a postcard to indicate their potential interest or disinterest in the study**.** The return postcard will contain pre-paid postage for ease of return.
- **Telephone:** RTI will establish a dedicated toll-free number with a recorded message that provides an option to hear the message in Spanish. A bilingual member of the project team will reply within one business day. Using a standard script and FAQs, the team member will explain the purpose of the study, address any questions or concerns, and explain the steps to participate.
- **Email**: Women can email and indicate preferred times for an interview. A bilingual member of the project team will reply within one business day.
- **Website:** RTI will develop a website where women can read about the study and schedule an interview. When women go to the website to learn about the study

and schedule an interview, online consent could be offered and then women would be asked to complete a short online survey comprising some of the basic questions. At the end of the survey, they could schedule a telephone interview. The telephone interview would have more in-depth questions.

For women who agree to participate in the study, RTI staff will schedule a one-hour telephone interview. Women will be asked how they prefer to be reminded about their interview appointment (i.e., telephone call, text, email).

Reminder letters/e-mails/calls/texts for the in-depth interviews will be sent to potential participants prior to the data collection, giving them directions for the telephone interview. The consent process will take place verbally and explained in plain language to account for participants with lower literacy. Directly prior to the interview, the interviewer will verbally review the consent form (**Attachment D**) and ask participants if they have any questions. Upon verbal consent, the interviewer will proceed with the interview. The in-depth interviews will be collected one time, over the telephone by a professionally trained moderator.

Each data collection for the in-depth interviews will last a total of 60 minutes. In addition to the moderator, an additional contractor will attend the sessions to take notes on a laptop computer. CDC staff member(s) may also attend to observe the in-depth interviews and triads in person or via video streaming. The in-depth interviews will be audio-recorded for the purpose of completing the final reports. All audio recordings will be destroyed after notes have been verified and no links will be maintained to any data collected.

Personal identifying information from potential participants participating in the in-depth interviews will be maintained and protected to the extent allowable by law. Only the state registries will have the contact information for women in the USZPIR. RTI will not have that 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 case ID that is not associated with any personal identifiers, and participant responses will not be attached to their identifiers. RTI will report findings in a summary report. Once the project ends, any identifying information about participants will be destroyed.

B3. Methods to Maximize Response Rates and Deal with No Response

The following procedures will be used for the in-depth interviews to maximize cooperation and achieve the desired participation rates:

- The registries in Virginia and Pennsylvania will send the recruitment materials participants**.**
- Reminder letters/e-mails/texts will be sent to participants with directions to the call-in line 1 to 2 days prior to the scheduled data collection.
- As a token of appreciation for their participation, respondents will be offered a $40 VISA check card.

B4. Test of Procedures or Methods to Be Undertaken

We have selected in-depth interviews as the most appropriate form of data collection. Qualitative methods 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. Furthermore, a qualitative approach will allow the researcher to capture subtle nuances in participants' attitudes, beliefs, and feelings related to the impact Zika has had on their family. The interview guide includes probes to ensure that input on specific items of interest is obtained while open-ended questions ensure that participants' responses and perceptions are fully addressed and captured (**Attachment E)**.

To estimate the burden for conducting the interview, RTI conducted a mock interview with a project team member. The project team member provided affirmative responses to most or all questions that led to further follow-up questions. Through this exercise, the burden estimate most closely resembled a maximum average burden because almost all interview questions were presented in the interview. In addition, the project team member deliberately read each item at a slow rate of speed. The estimated maximum average burden for the interview was 60 minutes.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The individuals consulted on technical and statistical issues related to data collection are listed below. The data will be collected and analyzed by the study contactor, RTI International.

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