Change Request
Sept 05, 2017

Information Collection Request: "ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia"

(OMB no. 0920-1190, exp. date 07/31/19)

Background and Justification

CDC is approved to collect information needed to better understand the adverse pregnancy, maternal and infant health outcomes associated with Zika Virus (ZIKV) during pregnancy and/or early infancy. This information includes multiple clinic visits to collect blood and urine, as well as interview administered questionnaires at every visit.

CDC obtained approval for information collection in June 2017 and is requesting a non-substantive modification request for the following changes:

1. To delete a question in the maternal follow-up questionnaire
2. To add 3-questions in the maternal follow-up questionnaire
3. Formatting changes to the eligibility form
4. Make minor edits to existing Spanish questionnaires

The proposed changes will allow for the most efficient capture of other tools used during the study without additional time burden. There is no change to the estimated burden per response. CDC plans to begin administering the revised instruments as soon as we receive approval. OMB approval is requested, effective immediately.

1. To delete the following question from the maternal follow-up questionnaire (Att B3 and C3).

18. Since your last study clinic visit, have you…?

Received oral sex from someone	☐$_1$ Yes ☐$_0$ No ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*
Performed oral sex on someone	☐$_1$ Yes ☐$_0$ No ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*
Had anal sex	☐$_1$ Yes ☐$_0$ No ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*

The purpose of this change is due to the sensitive nature of these questions and participants feeling offended. Although we may lose the ability to compare changes in sexual activity, the risk of losing participation is greater.

2. In lieu of this question, we would like to add 3 questions to the maternal follow-up questionnaire (Att B3 and C3) to be asked one time at the initial postpartum visit. These questions are to provide information on risk factors for Cytomegalovirus (CMV) infection results. The questions in English (Att B3) are as follows (Spanish version is in C3):

❖ **Only ask questions 18-20 at the initial postpartum visit (after she has given birth).**

Finally, I will ask you some questions about your contact with young children while you were pregnant.

18. During the pregnancy that just ended, did you regularly care for any children younger than 5 years of age? This could include your children, other children you cared for in your home, or children you cared for in other locations, such as in a school or childcare facility.

☐$_1$ Yes ☐$_0$ No ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*

❖ If Yes, go to #20.
❖ If No, "Thank you for answering the questionnaire. Do you have any questions?".

19. You mentioned that you regularly care for children younger than 5 years of age. These next questions ask about your interactions with these children. During the pregnancy that just ended, how frequently did:

You and a child share the same fork, spoon, or cup?	☐$_2$ Often ☐$_1$ Sometimes ☐$_0$ Never ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*
You and a child take bites out of the same piece of food?	☐$_2$ Often ☐$_1$ Sometimes ☐$_0$ Never ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*
You give food to a child by passing it from your mouth directly to their mouth (kiss-feeding)?	☐$_2$ Often ☐$_1$ Sometimes ☐$_0$ Never ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*

20. You mentioned that you regularly care for children younger than 5 years of age. During the pregnancy that just ended, how often did you kiss those children on the lips?

☐$_2$ Most days ☐$_1$ Some days ☐$_0$ Never ☐$_{77}$ *Don't know* ☐$_{88}$ *Refused*

3. We have added some formatting updates to the Woman Eligibility Screening Form (Att B1 and C1). Including a space to add age at time of enrollment, taking out option to only provide EDD or LMP, and adding language to stop if not eligible.

4. In addition, we have made minor skip pattern corrections to help improve the flow of the questions asked. The proposed skip pattern additions are illustrated below and the clean versions of the changed instruments are attached.

Enrollment Questionnaire Partners (Att C4):

19. En los últimos 3 meses, ¿con cuántas mujeres has tenido relaciones sexuales?

☐$_0$ Ninguna → **Pase a pregunta #24**
☐$_1$ 1
☐$_2$ 2
☐$_3$ 3 o más
☐$_{77}$ *No sé* → **Termina el cuestionario.**
☐$_{88}$ *No contestó* → **Termina el cuestionario.**

Enrollment Questionnaire Women (Att C2):

21. Durante los últimos 3 meses, ¿alguien en tu casa aparte de ti ha tenido síntomas del virus del Zika? Síntomas del virus del Zika significa tener 2 o más síntomas que no se puedan explicar por otras causas: fiebre, brote (sarpullido), ojos rojos, y dolor en las articulaciones.

☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*

→ ¿Fue ~~tu~~...

Tu esposo o pareja?	☐$_1$ Sí ☐$_0$ No ☐$_{66}$ No aplica ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Tu hijo/hija?	☐$_1$ Sí ☐$_0$ No ☐$_{66}$ No aplica ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Otra persona en la casa?	☐$_1$ Sí ☐$_0$ No ☐$_{66}$ No aplica ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó* *Si la respuesta es Sí, ¿quién fue?*_________________________________

22. En algún momento, ¿un médico o profesional de salud le ha dicho a alguien en tu casa aparte de ti que ha contraído el virus del Zika?

☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*

→ ¿Fue ~~tu~~...

Tu esposo o pareja?	☐$_1$ Sí ☐$_0$ No ☐$_{66}$ No aplica ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Tu hijo/hija?	☐$_1$ Sí ☐$_0$ No ☐$_{66}$ No aplica ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Otra persona en la casa?	☐$_1$ Sí ☐$_0$ No ☐$_{66}$ No aplica ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó* *Si la respuesta es Sí, ¿quién fue?*_________________________________

27b. Dengue

☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*

→ ¿Cuándo?

Menos de 3 meses atrás	☐$_1$ Sí → ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*	¿Fue dengue grave? ☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Entre 3 – 6 meses atrás	☐$_1$ Sí →	¿Fue dengue grave?

	☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
7 – 12 meses	☐$_1$ Sí → ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*	¿Fue dengue grave? ☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
13 meses – 5 años atrás	☐$_1$ Sí → ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*	¿Fue dengue grave? ☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Hace más de 5 años	☐$_1$ Sí → ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*	¿Fue dengue grave? ☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*

Infant symptoms questionnaire (Att C6):

- **Si respondió SÍ a <u>fiebre</u>, <u>brote (sarpullido)</u>, <u>ojos rojos,</u> o <u>dolor en las articulaciones</u> pase a la pregunta #8.**
- **Si no, pase a la pregunta #12.**

6b. Si contesto si, algún profesional de salud te dijo que tu bebé pudo haber tenido uno de los siguientes?

Virus del Zika	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Dengue	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Chikungunya	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Mayaro	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Fiebre amarilla	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Citomegalovirus	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ *No sé* ☐$_{88}$ *No contestó*
Rubeola	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ No sé ☐$_{88}$ No contestó
Toxoplasmosis	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ No sé ☐$_{88}$ No contestó
Síflis	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ No sé ☐$_{88}$ No contestó
Varicela	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ No sé ☐$_{88}$ No contestó
Parvovirus	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ No sé ☐$_{88}$ No contestó
Herpes	☐$_1$ Sí ☐$_0$ No ☐$_{77}$ No sé ☐$_{88}$ No contestó
Otro	☐$_1$ Sí, espifica: ___________________________ ☐$_0$ No ☐$_{77}$ No sé ☐$_{88}$ No contestó

12. ¿Desde la última cita del estudio de tu bebé, ha tenido algún otro síntoma que te gustaría contarme?