

Change Request

March 23, 2018

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

(OMB no. 0920-1190, exp. date 02/28/2021)

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 up to 2 years of age of the child. The child follow-up period will include standardized assessments and interview administered questionnaires at every visit.

CDC obtained approval for information collection on February 2, 2018. The following modifications are needed in addition to the approval obtained.

- In the Parent Child Follow-up Eligibility Form (Attachment B8;C8):
 - We added an inclusion criteria to enroll children in the long-term followup up to age 12 months. This criteria was added because of the time lapse between when children end the initial 0-6 months followup and enrollment in to the long-term followup. The first baby turned 6 months in November 2017, and we wanted to provide additional time for staff to contact the ZEN participants and to enroll the parent/child into the long-term followup.
 - We removed an exclusion criteria from the 6 month to 4 year follow-up study: "Child is not physically able to participate based on clinical judgment." Based on feedback from our INS collaborators, there was concern that this exclusion criteria might cause infants with congenital Zika syndrome, whose parents would like them to participate, to be excluded from the study.
 - We added an option to indicate case classification (e.g., laboratory confirmation of Zika infection during pregnancy) of the 900 children for the follow-up for study tracking purposes.

- In the Parent Consent and Child Permission for the follow-up (Attachment D5):
 - We included permission to video record the parent or the child during the developmental evaluation. Developmental assessment quality will be monitored through in-person and virtual assessments to ensure that all developmental assessments are being completed accurately and as intended. Some developmental assessments may be videotaped and examined by psychologists and other specialists with expertise in the developmental assessment tool. These videotapes will be used solely for study quality assurance purposes, and will not be used outside of the study.

 - Videotaping will be set up to minimize the individual identification of study families, and will occur if consent is provided. We anticipate monitoring the quality of about 10% of developmental evaluations only.

- In the Bayley Scales of Infant and Child Development (Attachment not included due to copyright reasons, tool described in B15)
 - Add administration at 6 and 9 months, in addition to 12, 18 and 24 months of age. This tool includes involvement of the parent and children through direct, manipulation-based

assessment of children's skills/abilities (physical, cognitive, language domains) and parent-report measures of early childhood development (psychosocial, adaptive behavior) across broad domains.

- o The social-emotional questionnaire component in the Bayley Scales is not available in Spanish; therefore, we want to use the Ages and Stages Questionnaire: Social Emotional Questionnaires only to replace that section in the Bayley Scales. We will use all other parts of Bayley Scales as is.
- In both the Parent Child Enrollment Questionnaire and the Parent Child Follow-up Questionnaire (Attachment B9;B10;C9;C10):
 - o We updated both questionnaires based on Spanish language changes and review of the coding for data entry into RedCap, including formatting and minor edits to the questionnaires.

o **The following question was added to the Parent Child Enrollment Questionnaire (B9, C9).**

8. *First, tell me about how often you have provided care for your child since your child's birth.*

a. *How many days per week do you provide care for your child?*

_____ days/week ₈₈ Refused

b. *On days when you provide care for your child, how many hours per day?*

_____ hours/day ₈₈ Refused

c. *Has someone helped you to provide care for your child on a regular basis since your child's birth?*

₁ Yes ₀ No ₈₈ Refused

o **The following nine questions were removed from Parent Child Enrollment Questionnaire (B9, C9).**

10. *How often is [Child's name] hard to feed?*

₁ All or most of the time

₂ Some of the time

₃ Rarely

₄ Never

11. *Below is a list of things that children sometimes do at meal times. Please tell me how often you think [Child's name] does each of these things. Response options include rarely or never, some of the time, or almost always.*

	<i>R</i> rarely or never ₀	<i>S</i> some of the time ₁	<i>A</i> Almost Always ₂	<i>D</i> don't know ₇₇	<i>R</i> Refused ₈₈	<i>Not</i> Applicable ₆₆
<i>Excessive spitting up</i>						
<i>Excessive drooling</i>						
<i>Gagging/retching/coughing</i>						

Difficulty swallowing						
Difficulty latching or sucking at breast or bottle						
Arching back/squirming away						
Refuses to open mouth						
Spits food out						
Eats too fast						
Turns head away from food/shakes head no						
Chews/sucks on food but does not swallow						
Swallows in "gulps"						
Any other feeding difficulties at mealtimes (Specify: _____)						

22. What was your relationship with [Child's name]'s father (mother) when he/she was born?

Were you:

- ₁ Married
- ₂ Free Union
- ₃ Single
- ₄ Divorced
- ₅ Widowed
- ₆ Other

(Specify: _____)

- ₇₇ Don't know
- ₈₈ Refused

23. When [Child's name] was born, were you and your baby's father (mother) living together....

- ₁ All or most of the time
- ₂ Some of the time
- ₃ Rarely
- ₄ Never
- ₈₈ Refused
- ₆₆ Not applicable

24. What is your relationship with [Child's name]'s father (mother) now? Are you:

- ₁ Married
- ₂ Free Union
- ₃ Single
- ₄ Divorced
- ₅ Widowed
- ₆ Other

(Specify: _____)

- ₇₇ Don't know
- ₈₈ Refused

25. Are you and [Child's name]'s father (mother) currently living together....

- ₁ All or most of the time
- ₂ Some of the time
- ₃ Rarely
- ₄ Never
- ₆₆ Not applicable

26. Are you in a new relationship?

- ₁ Yes, married to a new partner

- ₂ Yes, romantically involved with a new partner
₃ No
₆₆ Not applicable

27. Most people have disagreements in their relationships. Please indicate below the approximate extent of agreement or disagreement between you and your partner for each item on the following list.

	Always disagree (0)	Almost always disagree (1)	Frequently disagree (2)	Occasionally Disagree (3)	Almost Always Agree (4)	Always Agree (5)	Refused (88)
Philosophy of life							
Aims, goals, and things believed important							
Amount of time spent together							

28. How often would you say the following events occur between you and your mate?

	Never (0)	Less than once a month (1)	Once or twice a month (2)	Once or twice a week (3)	Once a day (4)	More often (5)	Refused (88)
Have a stimulating exchange of ideas							
Calmly discuss something together							
Work together on a project							

29. The dots on the following line represent different degrees of happiness on your relationship. The middle point, "happy", represents the degree of happiness in most relationships. Please circle the response which best describes the degree of happiness, all things considered, of your relationship.

0	1	2	3	4	5	6	8
Extremely unhappy	Fairly unhappy	A little unhappy	Happy	Very happy	Extremely happy	Perfect	Refused

o The following question was added to the Parent Child Follow-up Questionnaire (B10, C10).

5. First, tell me about how often you have provided care for your child since your last study visit.

a. How many days per week do you provide care for your child?
 _____ days per week ₈₈ Refused

b. On days when you provide care for your child, how many hours per day?
 _____ hours per day ₈₈ Refused

c. Has someone helped you to provide care for your child on a regular basis since your last study visit?
₁ Yes ₀ No ₈₈ Refused

o The following seven questions were removed from Parent Child Follow-up Questionnaire (B10, C10).

7. How often is [Child's name] hard to feed?

- ₁ All or most of the time
- ₂ Some of the time
- ₃ Rarely
- ₄ Never

8. Below is a list of things that children sometimes do at meal times. Please tell me how often you think [Child's name] does each of these things. Response options include rarely or never, some of the time, or almost always.

	Rarely or never ₀	Some of the time ₁	Almost Always ₂	Don't know ₇₇	Refused ₈₈	Not Applicable ₆₆
Excessive spitting up						
Excessive drooling						
Gagging/retching/coughing						
Difficulty swallowing						
Difficulty latching or sucking at breast or bottle						
Arching back/squirming away						
Refuses to open mouth						
Spits food out						
Eats too fast						
Turns head away from food/shakes head no						
Chews/sucks on food but does not swallow						
Swallows in "gulps"						
Any other feeding difficulties at mealtimes (Specify: _____)						

19. What is your relationship with [Child's name]'s father (mother) now? Are you:

- ₁ Married
- ₂ Free Union
- ₃ Single
- ₄ Divorced
- ₅ Widowed
- ₆ Other (Specify: _____)
- ₇₇ Don't know
- ₈₈ Refused

20. Are you and [Child's name]'s father (mother) currently living together....

- ₁ All or most of the time
- ₂ Some of the time
- ₃ Rarely

- ₄ Never
- ₆₆ Not applicable

21. Are you in a new relationship?

- ₁ Yes, married to a new partner
- ₂ Yes, romantically involved with a new partner
- ₃ No
- ₆₆ Not applicable

22. Most people have disagreements in their relationships. Please indicate below the approximate extent of agreement or disagreement between you and your partner for each item on the following list.

	Always disagree (0)	Almost always disagree (1)	Frequently disagree (2)	Occasionally Disagree (3)	Almost Always Agree(4)	Always Agree (5)	Refused (88)
Philosophy of life							
Aims, goals, and things believed important							
Amount of time spent together							

23. How often would you say the following events occur between you and your mate?

	Never (0)	Less than once a month (1)	Once or twice a month (2)	Once or twice a week (3)	Once a day (4)	More often (5)	Refused (88)
Have a stimulating exchange of ideas							
Calmly discuss something together							
Work together on a project							

24. The dots on the following line represent different degrees of happiness on your relationship. The middle point, "happy", represents the degree of happiness in most relationships. Please circle the response which best describes the degree of happiness, all things considered, of your relationship.

0	1	2	3	4	5	6	88
Extremely unhappy	Fairly unhappy	A little unhappy	Happy	Very happy	Extremely happy	Perfect	Refused

These changes will result in an overall decrease in burden from 14,210 hours to 14,735 hours (see burden table in Part A document).