

Parent-Child Eligibility for ZEN Follow-Up

Note: Before enrolling a parent and child, make sure you have enough supplies (study kits, paper forms, etc.)

Today's date: ____/____/____ (DD/MMM/YYYY)

City: Barranquilla Bucaramanga Tuluá

Clinic name: _____

Name of Person Completing the Form: _____

Keep the same ZEN ID number for the child as was used for the ZEN baby ID number. Mark this ZEN family code and child ID below:

ZEN Family Code: _____ ZEN Child ID: _____-_____-_____

A. Determination of selection into follow-up study

1. ZIKV status of mom/child:

- Mom: Laboratory evidence of ZIKV during pregnancy or within 10 days after birth
 - Child: Laboratory evidence of congenital ZIKV infection in infant from a specimen taken within 10 days of birth
 - Child: Born to a woman with 2 or more symptoms of ZIKV infection during pregnancy or within 10 days of birth without laboratory evidence in mother or child
- or**
- Child: Born to a mother with 1 or no symptoms of ZIKV infection and without any laboratory evidence of ZIKV infection during pregnancy or within 10 days of birth

2. Was child selected to be in the follow-up study?

- Yes
- No (if No, STOP. This form is complete.)

3. If selected, was parent/legal guardian of this child able to be contacted?

- Yes
- No (continue to attempt to contact the parent/legal guardian until the child is 11 months of age. If still unable, then STOP. This form is complete.)

B. Eligibility information

Inclusion Criteria

Is the enrolling individual a parent or legal guardian of the child enrolled in ZEN?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the enrolling parent/legal guardian speak Spanish?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the enrolling parent/legal guardian live with the child enrolled in ZEN?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the enrolling parent/legal guardian plan to live with the children for the duration of the study (four years)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the enrolling child < 12 months (1 year)?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Exclusion Criteria

Is the enrolling parent/legal guardian physically or psychologically unable to participate based on clinical judgement?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the enrolling parent/legal guardian unable or unwilling to consent to proposed study activities or give permission for the child from ZEN to engage in proposed study activities?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Eligibility Determination

The parent and child are eligible for the follow-up study. (All answers to inclusion criteria questions are Yes AND all answers to exclusion criteria questions are No.)

- Yes → Eligible
- No → Not Eligible --**STOP**, thank the participant. **See note to determine if another parent would be eligible to participate with the child.**
- Unsure → If unsure, then fill out Appendix E1 (contact information) and follow-up in one week.

Note. If the answers to any of the inclusion criteria are 'no' OR the answers to the last two items of the exclusion criteria are 'yes', determine if there is another parent or legal guardian that is interested in participating. If so, approach that parent about study participation and enrolling him or her and the child in the ZEN follow-up. Fill out another parent-child eligibility form when approaching the second parent/guardian.

Notes about eligibility determination: _____

If eligible, please complete the sections below.

Parent Informed Consent and Child Permission Determination

Did the enrolling parent provide his/her own informed consent AND provide permission for the child to participate? Parent consent AND Child permission must be received to be enrolled in the follow-up study.

- Yes → Enroll
- Unsure → If unsure, then fill out Appendix E1 (contact information) and follow-up in one week.
- No → If no, thank the parent for their time and note that they declined participation in the study.

Reason(s) for declining (*check all that apply*):

- Not interested
- Concerned about study protocol (safety, invasive)
- Concerns about time/transportation (Note: Discuss how the study will provide transport options.)
- Concerns about family member approval (e.g. partner, parents)
- Other concern: _____

C. Enrolled Parent and Child Information

Parent Information

	<u>Parent/Guardian (1)</u>	<u>Parent/Guardian (2)</u>
Last name		
First name(s)		
Date of birth	____ / ____ / ____ DD/ MMM /YYYY	____ / ____ / ____ DD/ MMM /YYYY
Relationship to the child		

ZEN Parent/Legal Guardian Participant Identification Numbers

Determine:

- If the participating parent or legal guardian was part of the pregnant woman or partner cohort. If so, assign the same participant ID number that this parent had previously.
- If the participating parent or legal guardian was not part of the pregnant woman or partner cohort. Assign a participant ID number following guidelines in SOP 2-02.

Mark their ZEN parent/legal guardian ID below:

ZEN Parent/Legal Guardian ID: _____ - ____ - _____

Infant/Child Information

Last names: _____

First name(s): _____

Date of birth: ____ / ____ / ____ Age of child at enrollment: ____ months ____ days
DD/ MMM / YYYY

Document number of Child: _____ Type of Document: _____

Child Development Study Kit

Did you give the enrolling parent a Child Development Study Kit before he/she left?

- Yes, he/she took it.
- Offered it to her, but he/she did not want/take it.
- Did not offer. → **STOP**. Do not enroll if no study kit is available. Schedule enrollment visit for another day.

If not offered, why?: _____