

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.)

Name of Person Completing the Form: _____

Document number of Child: _____ Type of Document: _____

ZEN Family Code: _____

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

Reason why child selected for follow-up study (select one):

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

Instituciones Prestadoras de Servicios de Salud (IPS) Information

Clinic name: _____

City: Barranquilla Bucaramanga Tuluá

Parent Information

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

Infant/Child Information

Last names: _____

First name(s): _____

Date of birth: _____

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 child enrolled in ZEN for the duration of the study (4 years)?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Exclusion Criteria

Is the child enrolled in ZEN physically unable to participate based on clinical judgement?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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 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 three items of the exclusion criteria are 'yes', determine if there is another parent or legal guardian that meets eligibility criteria. If no, 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.

Informed Consent and Permission Determination

Did the enrolling parent receive and provide his/her own informed consent and also provide permission for the child to participate?

- 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
- Concerns about family member approval (e.g. partner, parents)
- Other concern: _____

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 didn't 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?: _____

ZEN Participant Identification Numbers

Assign the same ZEN ID number for the child for the long-term follow-up that matches with the ZEN baby ID number. Mark this ZEN child ID below.

ZEN Child ID: _____ - - _____

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 ZEN-2-02.

Mark their ZEN parent/legal guardian ID below.

ZEN Parent/Legal Guardian ID: _____ - - _____