

## Flesch-Kincaid Reading Score – 7.8

### **Permission Form for Parent and Child to Participate in a Follow-Up Research Study**

**Title of the Investigation:** Zika en Embarazadas y Niños en Colombia (ZEN Colombia)

**Principal Investigators:**

- Dr. Martha Ospina, National Institute of Health (INS)
- Dr. Margaret Honein, US Centers for Disease Control and Prevention (CDC)
- Dr. Denise Jamieson, CDC

**Funding Source:** United States Agency for International Development and CDC

**Telephone number for the research study:** operational person, Helena Rodriguez Perea  
# 316-696-2924

**Email address for the research study:** hmrodriguez@ins.gov.co

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**Introduction:** The National Institute of Health of Colombia and the US Centers for Disease Control and Prevention (CDC) invite you to be a part of this research study.

#### **What is the purpose of this study?**

You have been selected to continue participation in ZEN. We want to learn more about Zika virus infection during pregnancy and how it affects the long-term health and development of children. We ask you questions about you and your family, and follow your child's development from six months of age to four years of age to understand how children with Zika are different from children without Zika.

#### **How long will my child and I participate?**

We will ask that you and your child participate until he/she is about 4 years of age. Completing all activities for you and your child may take 2-4 hours at each study visit.

#### **What does my child have to do if I decide to let him/her participate in this study?**

Your child will come with you to scheduled visits at about 6 months, 9 months, 12 months, 18 months, 24 months, 36 months, and 48 months of age. Depending on the visit, your child may be examined to check his or her growth, hearing, vision, and other development. We will also collect your child's blood at 6 months, 18 months, and 24 months of age to test for conditions that might affect his/her health or development, such as previous Zika infection, iron, mercury, and lead levels. This sample and test is in addition to testing that your child's health care provider may ask of you. Cerebrospinal fluid (fluid found in the backbone) will not be obtained from your child as part of this research. If you and your child's doctor decide to take cerebrospinal fluid (liquid found around the spine) from your child, we will ask for a sample of the already collected fluid to test for Zika virus.

#### **What do I have to do if I decide to participate in this study?**

You will come with your child to scheduled visits. We will ask you questions about your child's health and development. We will also ask you questions about you and your family environment, including questions about support, your relationships, and any depressed feelings you might be having. You will be asked to take an intelligence test.

#### **Are there any risks to my child if I decide to let him/her participate in this study?**

The risks of being in this study to your child are minimal. The risks of taking blood include pain, bruising, redness and swelling of the vein and infection. Infection is rare, and the possibility of this occurring is less than 1 in 1,000. You may discover that there is a problem with the health or development of your child. We can provide counseling support to help you.

**Are there any risks to myself if I decide to participate in this study?**

The risks of being in this study to you are minimal. We will ask you questions about you and your family life, including about your emotional health and stress. If any of these questions make you feel uncomfortable, you are free to not answer. You may discover that you have a lot of difficulties. We can provide counseling support to help you.

**Are there benefits to my child if I decide to let him/her participate in this study?**

Your child will receive health and developmental assessments more frequently than children who are not in this study. These results may require additional follow-up from his/her clinician. We will share your child's assessment results with you so that you can share this information with his/her clinician or insurance company. Your child's results will also include information from our study staff about recommendations for follow-up and referrals for services to help you access a team of professionals that will help refer your child to clinical care, if necessary.

**Are there benefits to me if I decide to participate in this study?**

You will receive depression screening more frequently than parents who are not in this study. Your results may require additional follow-up with your personal clinician. We will share your results with you so that you can share this information with your clinician or insurance company. Your results will also include information from our study staff about recommendations for follow-up and referral for services to help make sure you have access to a team of professionals, if needed.

**What are the costs to participate in this study?**

There will be no costs for you or your child to participate in the study. You and your child will not have to pay for any study visits or testing. However, there may be other costs to you, such as losing time away from work. During the visits, we may provide you and your child with snacks and drinks.

**Will the information that is collected be kept private?**

The information you give us will be kept strictly confidential to the extent allowed by law. When the results of this research are presented, we will not include any information that can identify you or your child. The study has an Assurance of Confidentiality, so your information cannot be shared with anyone outside of the study, including if an official of the court, the government, or law asks for it. At the end of this permission form, we will ask if you provide authorization to release your and your child's results to an appropriate clinician or insurance company. Employees of CDC and INS, experts and contractors working for the two entities, may review information sent through computer networks to assess security. Conduct of the study is regulated by the ethical considerations for health research within Resolution 8430 of 1993 of the Ministry of Health, which is a requirement under Colombian law.

**What happens if my child or I are injured in this study?**

Problems may come up during any research as already mentioned. This can include risk of harm (for example pain or bruises where the blood was drawn) even if following protocols properly. If this happens, the researchers will help your child to receive proper attention for the injury. By signing this form, you and your child do not give up any of your legal rights.

**Who should I call if I have questions about the study, or if I think that my child or I are sick or harmed by the study?**

Please contact Helena María Rodríguez Perea at INS at 316 696 2924.

**Who should I call if I have questions about my or my child's rights as research volunteers?**

If you have any questions about your or your child's rights as participants in this study, please contact Yamileth Ortiz at INS at 322 400 8406. Leave a message with your name, telephone number, and refer to INS Protocol # 26-2016, and she will return your call.

**Does my child or I have to participate in this study?**

You can stop your and your child's participation in this study or drop out at any time without your or your child losing any medical care or benefits you or your child would normally have.

**Parent Follow-up Consent Form:**

**Parent study ID:** \_\_\_\_\_

By signing or making a mark on this consent/assent form, you accept that you have read or that another person has read the form to you, that you have had the opportunity to ask questions about everything you did not understand, and that you voluntarily agree **for you** to participate in this study.

\_\_\_\_\_  
Signature of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Full name of the mother, father or guardian of the ZEN child

The participant:             Knows how to read             Does not know how to read

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Signature of Research Team Member Obtaining Permission

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Research Team Member Obtaining Permission

**Child Follow-up Permission Form:**

**Child study ID:** \_\_\_\_\_

By signing or making a mark on this permission form, you accept that you have read or that another person has read the form to you, that you have had the opportunity to ask questions about everything you did not understand, and that you voluntarily agree for **your child**, \_\_\_\_\_,

Child's Name

to participate in this study.

\_\_\_\_\_  
Signature of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Full name of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Signature of Research Team Member Obtaining Permission

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Research Team Member Obtaining Permission

**Child storage of the samples and future tests**

**Child study ID:** \_\_\_\_\_

If you agree, the body fluid samples of your child will be stored and can be used for further research related to Zika virus not currently a part of this study. At this point, we expect that stored samples will be used to test for new methods to detect Zika virus, to evaluate the body's response to Zika infection, or to examine factors that can affect the health of the child. Other information about your child will not be stored with the sample. If we would like to use these samples for other reasons not specified above, we will contact you to get your permission.

You do not need to agree with storing your child's samples to participate in the study. If you agree, we will store the samples until they are used up or destroyed.

You can change your mind and decide not to allow the storage of your child's samples. If this occurs, we ask that you contact the study and ask that your child's samples be destroyed.

**Blood samples from your child:**

\_\_\_\_\_ **I agree** that any blood samples from **my child** can be stored and used for the specified research purposes in the future.

\_\_\_\_\_ **I do not agree** that any blood samples from **my child** can be stored and used for the specified research purposes in the future.

**Cerebrospinal fluid samples (if taken by a doctor's decision):**

\_\_\_\_\_ **I agree** that any of the cerebrospinal fluid samples already taken from **my child** can be stored and used for the specified research purposes in the future.

\_\_\_\_\_ **I do not agree** that any of the cerebrospinal fluid samples already taken from **my child** can be stored and used for the specified research purposes in the future.

**Tissue from your child, in the event of death (if taken by doctor's decision):**

\_\_\_\_\_ **I agree** that any of the tissues from **my child**, in the event of his or her death, be stored and used for the specified research purposes in the future.

\_\_\_\_\_ **I do not agree** that any of the tissues from **my child**, in the event of his or her death, be stored and used for the specified research purposes in the future.

If we test these stored samples in the future and find a result that could affect the health of your child, would you like for us to give you the test result?

Child study ID: \_\_\_\_\_

**Results of samples from your child:**

\_\_\_\_\_ **Yes**, I would like to know the result.

\_\_\_\_\_ **No**, I would not like to know the result.

\_\_\_\_\_  
Signature of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Full name of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Signature of Research Team Member

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Research Team Member

**Child Medical Records Release**

**Child study ID:** \_\_\_\_\_

As part of the study we would like to get a copy of your child’s medical records so that we can know about your child’s health.

We need your permission to look at your child’s medical and developmental health records. These may include records from you or your child’s primary doctor or a specialist. We are asking to access these medical records until data collection for the study ends. If we cannot obtain your child’s medical records from the clinic or hospital, we may contact your insurance company to gain access to the medical records. If we need to access the records after the end of data collection, we will contact you to ask your permission. You are free to say no. You are also free to withdraw your permission before the study is over.

Release of **your child’s** medical records:

\_\_\_\_\_ **I agree** to release **my child’s** medical records for the research study

\_\_\_\_\_ **I do not agree** to release **my child’s** medical records for the research study

\_\_\_\_\_  
Signature of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Full name of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Signature of Research Team Member

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Research Team Member



**Parent and Child Study Results Release**

**Parent study ID:** \_\_\_\_\_

**Child study ID:** \_\_\_\_\_

As part of the study we sometimes may need to discuss you or your child’s study results with your clinicians or insurance companies. We need your permission to release any results or to discuss you or your child’s results with your clinicians or insurance companies. This might occur if, in addition to providing you results and our recommendations for follow-up, we need to do more follow-up or assist you with arranging referrals for other services. You are free to say no. You are also free to withdraw your permission before the study is over.

Release of **your** study results to your clinician or insurance company:

\_\_\_\_\_ **I agree** to release **my** results for the research study

\_\_\_\_\_ **I do not agree** to release **my** results for the research study

Release of **your child’s** study results to their clinician or insurance company:

\_\_\_\_\_ **I agree** to release **my child’s** results for the research study

\_\_\_\_\_ **I do not agree** to release **my child’s** results for the research study

\_\_\_\_\_  
Signature of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Full name of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Signature of Research Team Member

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Research Team Member

**Parent and Child Video Recording Release**

**Parent study ID:** \_\_\_\_\_

**Child study ID:** \_\_\_\_\_

To ensure that the assessments are of high quality, we may ask to record a video of you and/or your child during a study visit. This recording will only be used to make sure your child's development is being tested correctly, and the recording will not be seen or released outside of study staff to keep your privacy. We will destroy the recording after the quality review is done. You are free to say no. You are also free to withdraw your permission before the study is over.

Permission for us to record a video of you for quality review only

\_\_\_\_\_ **I agree** to be recorded

\_\_\_\_\_ **I do not agree** to be recorded

Permission for us to record a video of your child for quality review only

\_\_\_\_\_ **I agree** to allow my child to be recorded

\_\_\_\_\_ **I do not agree** to allow my child to be recorded

\_\_\_\_\_  
Signature of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Full name of the mother, father or guardian of the ZEN child

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Signature of Research Team Member

\_\_\_\_\_  
Date (DD/MMM/YYYY)

\_\_\_\_\_  
Printed Name of Research Team Member