Flesch-Kincaid Reading Score – 7.8

Permission Form for Infant to Participate in a 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)
Email address for the research study:

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?
The purpose of this study is to learn more about Zika virus infection during pregnancy and how it affects the health of your baby. We will do this by testing for Zika through the first six months of your baby's life to understand how Zika infected babies are different from non-infected babies.

How long will my baby participate?
We will ask that your baby participates until age 6 months.

What does my baby have to do if I decide to participate in this study?
You will come with your baby to scheduled visits to assess the baby's growth, hearing, vision and development. These visits will occur when the baby is about 1 month, 2 months, 3 months, and 6 months of age. You will also be asked to collect a urine sample from your baby to be tested for Zika virus about every two weeks. You will be asked questions about whether your baby has any possible Zika symptoms. If your baby becomes sick with symptoms of Zika, you will be asked if your baby can give a blood sample. This sample and test is in addition to testing that your baby's health care provider may ask of you. Cerebrospinal fluid will not be obtained from your baby as part of this research. If you and your baby's doctor decide to take cerebrospinal fluid from your baby, we will ask for a sample of the already collected fluid to test for Zika virus.

Are there any risks to my baby if I decide to participate in this study?
The risks of being in this study are minimal. The risks of taking blood include pain, bruising, redness and swelling if the vein and infection. Infection is rare, and the possibility of this occurring is less than 1 in 1,000. During the study, we may ask questions that may make you feel uncomfortable, if so you do not have to answer these questions. You may discover that your baby has Zika virus or that there is a problem with the health of your baby. We can provide counseling support to help you.

Are there benefits to my baby if I decide to participate in this study?
Your baby will receive testing for Zika virus more frequently than people who are not in this study. You will be provided information about Zika virus and your baby may benefit from additional health and developmental assessments. You will have access to a team of professionals that will help refer you to clinical care, if necessary.

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 baby. 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. Employees of INS are governed by the ethical considerations for health research within Resolution 8430 of 1993 of the Ministry of Health.

What happens if my baby is 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 baby to receive proper attention for the injury. By signing this form, you and your baby 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 baby is 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 baby's rights as a research volunteer?

If you have any questions about your rights as a participant in this study, please contact Helena María Rodríguez Perea at INS at 316 696 2924. Leave a message with your name, telephone number, and refer to INS Protocol # 26-2016, and she will return your call.

Does my baby have to participate in this study?

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

Infant Permission Form: **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 baby to participate in this study.

_____ _____
Signature of the mother, father or guardian of the baby participating in the study Date (DD/MMM/YYYY)

_____
Full name of the mother, father or guardian of the baby participating in the study

_____ _____
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

Storage of the samples and future tests **Study ID: _____**

If you agree, the body fluid samples of your baby 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 newborn. Other information about your baby 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 baby'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 baby's samples. If this occurs, we ask that you contact the study and ask that your baby's samples be destroyed.

Blood and urine samples from your baby:

_____ **I agree** that any of the samples from **my baby** (blood, urine) can be stored and used for the specified research purposes in the future.

_____ **I do not agree** that any of the samples from **my baby** (blood, urine) can be stored and used for the specified research purposes in the future.

The cerebrospinal fluid samples (if it was taken by a doctor's decision):

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

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

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

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

The samples of your baby:

_____ **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 baby participating in the study — Date (DD/MMM/YYYY)

_____
Full name of the mother, father or guardian of the baby participating in the study

_____ _____
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

Medical Records Release **Study ID**_____

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

We need your permission to look at your baby's medical records. We are asking to access these medical records until data collection for the study ends. 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 baby's** medical records:

_____ **I agree** to release **my baby's** medical records for the research study

_____ **I do not agree** to release **my baby's** medical records for the research study

_____ _____
Signature of the mother, father or guardian of the baby participating in the study Date (DD/MMM/YYYY)

_____
Full name of the mother, father or guardian of the baby participating in the study

_____ _____
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