Flesch-Kincaid Reading Score – 7.8

Consent for Participating in a Research Study
Title of the Research: Zika en Embarazadas y Niños en Colombia (ZEN Colombia)
Principal Investigators:

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

Financing Source: US Agency for International Development (USAID) and US CDC
Telephone number for 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. We will do this by testing for Zika during pregnancy to understand why some women contract Zika virus and how it can affect your health and the health of your baby.

How long will you need me?
You are being asked to participate starting in the first three months of your pregnancy through six months after the birth of your baby. You are also being asked to allow your baby to participate through the first 4 days after his/her birth. After your baby is born, we will ask for your permission to allow your baby to continue participating until age 6 months.

What do I have to do if I decide to participate in the study?
You will be asked to give a blood sample about once a month during pregnancy to test for Zika virus and to provide a blood sample at enrollment to test for other infections (syphilis, HIV, toxoplasmosis, etc.) and Zika virus antibodies. You will also be asked to collect a urine sample about once a month to be tested for Zika virus. If you become sick with symptoms of Zika, you will be asked to give a blood sample. If you have Zika virus, you will be asked to give a blood sample every 2 weeks until you no longer have the Zika virus in your blood. In this research, we will not take amniotic fluid samples. If you and your doctor decide that this sample needs to be taken, we will ask your health care provider for a sample of your amniotic fluid that has already been collected to test for Zika virus or to be stored for future testing. If you have a pregnancy loss, you may be asked to give a blood sample. At delivery or within the first 4 days after delivery, you will be asked to provide a blood sample to be tested for Zika, other infections, and Zika virus antibodies. These samples and tests are in addition to testing that your prenatal care provider may ask of you. You will be asked questions about your health and behaviors, including Zika symptoms that you may have at every study visit. If you have a partner that lives with you, we may ask you to contact him to invite him to participate in this study.

What will my baby have to do to participate at delivery?

At delivery or up to 4 days after delivery, we will consult with your baby's doctor to identify any health problems, collect a blood sample from your baby, and do an ultrasound of your baby's head. 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 fluid that has already been collected to test for Zika virus.

Are there risks to me if I decide to participate in the study?

The risks of being in this study 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 persons. During the study, we may ask questions that may make you feel uncomfortable, if so you do not have to answer these questions. You, your partner or your baby may find out you have Zika virus or that there is a problem with your baby's health. We can provide you counseling support to help you.

Are there benefits if I accept to participate in the study?

You will receive Zika virus testing more often than people who are not in the study. You will have access to a team of professionals that will refer you to clinical care , if necessary.

Will the information I give you be kept private?

The information you give us will be kept strictly confidential to the extent allowed by law. When results from this research are presented, we will not include any information that can identify you. The study has an Assurance of Confidentiality, so your information cannot be shared with anyone outside of the study, even if an official of the court, the government or law requests it. Employees of the INS are regulated by ethical considerations for health research within Resolution 8430 of 1993 of the Ministry of Health.

What will happen if I have injuries from 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 you to receive proper attention for the injury. By signing this form, you do not give up any of your legal rights.

Who should I call if I have questions about this study or think I may have gotten sick or been 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 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.

Do I have to participate in this study?

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

Participant consent: **Study ID:** _____

By signing or making a mark on this consent form, you agree that you have read it, or had someone read it you, you had the chance to ask questions about anything you do not understand, and that you voluntarily agree to participate in this study.

_____ _____
Signature of Research Participant Date (DD/MMM/YYYY)

_____
Printed Name of Research Participant

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 Consent Date (DD/MMM/YYYY)

_____
Signature of Research Team Member Obtaining Consent

Storage of samples and future testing **Study ID: _____**

If you agree, your samples of bodily fluids or bodily fluids of your baby will be stored and can be used for further research related to Zika virus that is not currently a part of this study. At this point, we expect stored samples will be used to test new methods to detect Zika virus, to evaluate the body's response to Zika infection, or to examine factors that can affect pregnancy or the health of the newborn. Other information about you will not be stored with your 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 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 to not permit the storage of your samples. If this occurs, we ask that you contact the study and ask that the samples be destroyed.

Your blood and urine samples:

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

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

Your amniotic fluid sample (if taken by doctor's decision):

_____ **I agree** that **my** amniotic fluid sample be stored and used for the specified research purposes in the future.

_____ **I do not agree** that **my** amniotic fluid sample 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 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 from **my baby** can be stored used for the specified research purposes in the future.

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

_____ **I agree** that any of the tissues from **my baby** (from spontaneous abortion, fetal loss, or voluntary interruption of pregnancy) can be stored and used for the specified research purposes in the future.

_____ **I do not agree** that any of the tissues from **my baby** (from spontaneous abortion, fetal loss, or voluntary interruption of pregnancy) can be stored and used for the specified research purposes in the future.

Study ID_____

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

Your samples:

_____**Yes,** I would like to know the result.

_____ **No**, I do **not** want to know the result.

_____ _____
Signature of Research Participant Date (DD/MMM/YYYY)

_____
Printed Name of Research Participant

_____ _____
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

Contacting Male Partner for Study Participation Study ID_____

To learn more about how Zika virus can be transmitted between sexual partners, we would like to invite your partner to participate in the study. May we contact your partner about enrolling in the study?

_____ Yes, I agree my partner can be contacted
Partner name and contact information (phone or email):
_____
_____
_____

_____ No, I do not agree to my partner being contacted

_____ I do not have a partner or one that that lives with me

_____ _____
Signature of Research Participant Date (DD/MMM/YYYY)

_____
Printed Name of Research Participant

_____ _____
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 medical records so that we can know about your health during your pregnancy. We would also like a copy of your baby's medical records from the delivery and immediate following the birth, to look for any health problems.

We need your permission to look at your and 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 **my** medical records:

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

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

Release of **my 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 Research Participant Date (DD/MMM/YYYY)

_____
Printed Name of Research Participant

_____ _____
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