

## Flesch-Kincaid Reading Score – 7.8

### Consent and Parental Permission to Participate in a Research Study

**Title of Study:** Zika en Embarazadas y Niños en Colombia (ZEN Colombia).

**Principal Study Investigators:**

- Dr. Martha Ospina, Instituto Nacional de Salud
- Dr. Margaret Honein, U.S. Centers for Disease Control and Prevention
- Dr. Denise Jamieson, U.S. Centers for Disease Control and Prevention

**Funding Source:** U.S. Agency for International Development (USAID) and CDC

**Study Telephone Number:** [number]

**Study Email:** [email]

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#### **What I should know about this study?**

We are asking you to take part in a research study because you are in the first trimester of your pregnancy. We are also asking your permission to have your baby participate in the study after he or she is born. Being part of the study is optional. You may decide not to be in the study for any reason. Deciding not to be in the study or leaving the study before it is done will not affect your health care. You do not have to be in the research study to receive health care.

Details about this study are below. It is important that you understand this information so that you can make an informed decision about being in this study. You will be given a copy of this form. You should ask any questions you have about this study at any time.

#### **Who is doing this study?**

El Instituto Nacional de Salud de Colombia (INS) and the U.S. Centers for Disease Control and Prevention (CDC) are doing this research study. The names of the study investigators are above.

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

The purpose of this study is to learn more about Zika virus during pregnancy. We will be testing pregnant women for Zika virus to find out why some women get Zika virus infection in pregnancy and how it might affect their health and their baby's health. We will also be looking at behaviors and health conditions that may predict why some people get Zika virus but others do not, and why Zika affects the health of some women and their pregnancies, but not others.

#### **How many people will be in this study?**

About 5,000 pregnant women and their babies will be in this study.

#### **How long will you need me?**

The study will start in the first trimester of your pregnancy and last at least 6 months after your baby is born.

During your pregnancy:

- You will come to the clinic every month for a prenatal visit. Depending on what tests your doctor does, these visits may take up to 60 minutes each.
- Every month, about two weeks after your visits to the clinic, you will have an appointment with study staff at your home until you reach about 32 weeks of gestation. These visits might take up to 15 minutes each.
- If you have symptoms of Zika virus, you will be asked to make an appointment at the clinic to get tested for Zika virus and have a physical examination. This visit may take up to 15 minutes.
- If you have Zika virus, you will come to the clinic every other week to be tested for Zika virus until the virus is gone from your body. This could take between 2 and 12 weeks. Each of these visits should take about 15 minutes. If you are not able to come to the clinic for testing, it may be possible to arrange for study staff to come to your home.
- You will receive an ultrasound 3 times during your pregnancy as a part of your routine prenatal care. These could take up to 60 minutes each.
- If you have Zika virus, you will have an ultrasound once per month during your pregnancy to check on the health of your baby. These could take up to 60 minutes each.
- The results of tests conducted during pregnancy that could affect your healthcare will be provided to you by your healthcare provider.

After your baby is born:

- You will have a visit at birth to check on you and the health of your baby. This visit may take up to 60 minutes.
- You will have an appointment with study staff 3 days after your baby is born. This visit may take up to 60 minutes.
- You will take your baby for an appointment at the clinic when your baby is 1 month, 2 months, 3 months, and 6 months old to check on the health of your baby. Depending on what tests your baby's doctor does, these visits may take up to 60 minutes each.
- Every 2 weeks from the time your baby is born until your baby is 6 months old, your baby will have an appointment at home with study staff. These visits might take up to 15 minutes each.
- The results of tests conducted on your baby after birth that could affect their healthcare will be provided to you by his or her healthcare provider.

**What do I need to do if I decide to be in this study?**

If you agree to be in this study, you will go to the following visits:

**1. Enrollment visit (today or within the next week)**

At today's visit, you will do the following:

- Review this form and ask any questions that you have about the study.
- Sign this form.
- Provide information about how the study staff can contact you.
- If you have not had a pregnancy test yet, we will test your urine to make sure that you are pregnant. We will give you a sterile cup to collect a urine sample.
- Have a routine prenatal care visit with your healthcare provider.
- If you have not had an ultrasound yet, we might perform an ultrasound to see how far along you are in your pregnancy.

- Complete a questionnaire including information about your health and behaviors.
- Complete a questionnaire asking you about any Zika symptoms you have.
- Blood collection. We will collect about 2 teaspoon of blood. We will test your blood for Zika virus, and for other infections. We will store some of your blood for later testing for antibodies (proteins in the blood that fight germs) to Zika virus.

At the end of this visit, we will schedule your first home visit. We will also give you a collection kit which has all the supplies you need for the home visit. You will also receive a study kit, which has a contact card with a number to call if you feel sick with Zika symptoms or to identify yourself as a study participant. If you have a male partner who you live with, we will give you information about our study of male partners. We will ask you if you would like to pass information along to him and/or if we may contact him directly to see if he would like to participate in the study with you.

## **2. Routine study visits**

We will ask you to come back to the clinic once every month during your pregnancy. At this visit, you will be tested for Zika virus. We will also ask you questions about your health and behaviors, including if you have Zika symptoms.

## **3. Home visits**

Study staff will come to your home every 4 weeks until around the 32 week of pregnancy. At these home visits you will do the following:

- Complete a questionnaire asking you about any Zika symptoms you have.
- Urine collection. We will give you a sterile cup to collect a urine sample for Zika testing.

## **4. Clinic visit if you have symptoms of Zika virus**

We will schedule a clinic visit if you have symptoms of Zika virus. At this visit, you will do the following:

- Complete a questionnaire asking you about any Zika symptoms you have.
- Blood collection. We will collect about 1 teaspoon of your blood to test for Zika virus

## **5. Clinic visits if you have Zika virus**

If you have Zika virus, we will ask you to come to the clinic every other week to be tested for Zika virus. These visits will continue until you do not have any Zika in your body. At each visit, you will do the following:

- Complete a questionnaire asking you about any Zika symptoms you have.
- Blood collection. We will collect about 1 teaspoon of your blood to test for Zika virus.

Women who have Zika virus will be asked to have an ultrasound once per month for the rest of the pregnancy to check on the baby's growth. At the end of each visit, we will schedule your next visit.

## **6. Amniocentesis**

Having an amniocentesis is not a part of this study. But, if you and your healthcare provider decide that you should have an amniocentesis, we will ask your healthcare provider if we can test a sample of your amniotic fluid (about 1 teaspoon) for Zika virus. If you give us permission, we might store any fluid provided for future testing.

## **7. Miscarriage, stillbirth, or termination of pregnancy**

If you experience a miscarriage or stillbirth, or decide to end your pregnancy, we realize that it may be a difficult time for you and your family. If you come to the clinic within 7 days of the loss of your pregnancy, we may collect your blood to test for Zika virus and ask you questions about Zika virus symptoms. We may ask your healthcare provider if we can test a sample from the baby's tissue (if it is available) for Zika virus. If you give us permission, we might store any samples of the baby's tissue for future testing.

## **8. Delivery**

At the birth, we will ask your healthcare provider to do the following:

- Measure the head circumference of your baby.
- Examine your baby to see if your baby has any health problems.
- Do an ultrasound of your baby's head to look for any problems with the brain
- Take a sample of blood from you (about two teaspoons) and your baby (about one teaspoon) to test for Zika virus. We will also test your baby's blood for antibodies (proteins in the blood to fight germs) to Zika virus. We will store some of your blood for later testing for antibodies to Zika virus.

Collecting cerebrospinal fluid from your baby is not a part of the study. But, if you and your baby's healthcare provider decide to do a spinal tap on your baby, we will ask for less than half a teaspoon of this fluid for Zika testing. If you give us permission, we may store any fluid for future testing.

## **9. Day 3 visit**

About 3 days after your baby is born, we will schedule a visit to see you and your baby. At this visit, we will ask you to do the following:

- Complete a questionnaire asking you about your health and behavior. You will also be asked to complete a questionnaire about any Zika symptoms you have.
- Complete a questionnaire asking you about any Zika symptoms your baby has had.
- Blood collection. If not done at the time of birth, we will collect blood from you (about two teaspoons) and your baby (about one teaspoon) to test for Zika virus. We will also test your baby's blood for antibodies (proteins in the blood to fight germs) to Zika virus. We will store some of your blood for later testing for antibodies to Zika virus.

We will ask to do the following to check on the health of your baby:

- Test your baby's hearing.
- Look at your baby's eyes and check your baby's vision.
- Check your baby's reflexes.
- Measure the head circumference of your baby.

- If the ultrasound of your baby's head was not done at delivery, we will do it at this visit or refer you and your baby to a clinic where this can be done.

At the end of the visit, we will schedule your baby's next study visit.

## **10. Routine baby visits**

We will ask you and your baby to come to the clinic when your baby is 1 month, 2 months, 3 months, and 6 months old. At this time, your baby might also see their healthcare provider for a routine check-up.

At each visit, we will ask to do the following to check on the health of your baby:

- Check your baby's reflexes.
- Measure your baby's growth (head and body).
- Check if your baby is doing things that a baby should be doing at that age (for example, smiling or rolling over).

We will also ask you to answer some questions about:

- Zika virus symptoms your baby might have had recently.
- Zika virus symptoms you might have had recently.
- Breastfeeding.

At the 6 month visit, we will also ask to check your baby's hearing and vision.

At the end of each appointment, we will schedule your next home and clinic appointments.

## **11. Infant interval home visits**

Study staff will come to your home every 2 weeks until your baby is 6 months old. At these home visits we will ask you to do the following:

- Complete a questionnaire asking you about any Zika symptoms your baby might have had.
- Urine collection. We will give you a kit that includes instructions so that you can collect urine from your baby for Zika testing.

At the end of each visit, we will give you any supplies you need for the next urine collection and will schedule your next appointment.

## **12. Infant symptoms of Zika virus**

If your baby has symptoms of Zika virus, we will ask that you come to the clinic so that your baby can be examined by a healthcare provider. At this visit, we will also ask to do the following to check on the health of your baby:

- Blood collection. We will collect about 1 teaspoon of blood (divided in 2 tubes) to test your baby's blood for Zika virus.
- We will also ask you to answer questions about any symptoms of Zika virus your baby might have had recently.

### **13. Medical records**

We will ask to read your medical records so that we can find out what kind of health problems you had and what kinds of medications you used during pregnancy or after your pregnancy ended. We will also ask to see your baby's medical records so that we can find out what kind of health problems your baby has and what kind of medications he or she takes. In the unfortunate event that your baby does not live past his or her 6<sup>th</sup> month birthday, we will ask you for a copy of the death certificate.

#### **Are there any risks to me or my baby if I decide to be in this study?**

The risks of being part of this study are low:

- You or your baby might have some pain or bruising after we collect blood.
- You or your baby might get an infection after we collect blood. This is rare, and the chance of this happening is less than 1 in 1,000.
- Study staff will ask you questions about yourself and your medical history and about your baby and their medical history. Some of these questions might make you feel uncomfortable. If this happens, you do not have to answer these questions.
- While you are in this study, you might find out that you, your partner, or your baby have Zika virus or that there is a problem with your baby's health. This might affect your mental health. We will provide you with counseling resources to help you cope with this news.
- It is unlikely, but possible, that your information or your baby's information could be unintentionally shared with people who do not have permission to see it. We will take every step we can to prevent this from happening.

You will have to spend additional time at the clinic for visits, or at home to participate in the study. Study staff will try to arrange your visits so that they are as convenient to your schedule as possible. If you think you have gotten sick or harmed by this study, you should contact the Colombian study investigator. The study investigator's contact information is provided above.

#### **Are there any benefits to me from being in this study?**

You and your baby will be tested for Zika virus more often than people who are not in this study, which means that you will be able to find out if you or your baby have Zika virus even if you do not have any symptoms. You can expect to have test results within a week. You may also benefit from more medical care, such as additional ultrasounds. You might also indirectly benefit from new information about Zika virus that is found in this study.

#### **What alternatives do I and my baby have to participating in this study?**

You and your baby do not have to participate in this study. If you do not participate, you and your baby will continue to receive normal medical care.

#### **What if you learn about new findings or information during the study?**

We will give you any new information that might affect your willingness to continue your or your baby's participation.

#### **Will the information I give you be kept private?**

We will protect your privacy in the following ways:

- We will use a participant identification number instead of your name or cedula on all forms, to label all body fluid samples, and in the study databases. We will not store your name, cedula, or other information that could identify you in the same place we store medical information we collect about you.
- We will store study forms in a locked file cabinet that only study staff can access.
- We will store electronic records on a password-protected database that only study staff can access.
- When we present the results of this research, we will not include any information that could identify you.
- We will do all that we can to keep your information private. However, there may be times when the law in Colombia requires that we share this information. If this happens, we will take all the steps we can to protect your privacy.
- Your information might be reviewed by officials from INS, CDC, the study sponsor, or the government for quality control or safety.
- CDC has an Assurance of Confidentiality for this study. This means that CDC employees cannot share your information with anyone outside of the study, even if a judge, government, or law enforcement official asks for it. Because INS employees are not covered by this Assurance of Confidentiality there may be times when the law in Colombia requires that we share this information.

### **What will happen if I am injured by this research?**

All research involves a chance that something bad might happen to you. This may include the risk of injury. Even with safety measures in place, you or your baby might develop an injury from being in this study. If this happens, the researchers will help you or your baby get medical care. Costs for this medical care will be covered by you or your insurance company. The study sponsor does not have any money set aside to cover your or your baby's medical bills. By signing this form, you and your baby do not give up any of your legal rights.

### **What if I want to stop or study investigators want to stop me before my part in the study is complete?**

You or your baby can stop being in this study at any time.

The study investigators can also ask you or your baby to stop being in the study. This could be because you or your baby no longer meet the criteria to be included in the study or because the study has stopped. If you or your baby are no longer in the study, you will still receive your regular medical care.

### **Will I receive anything for being in this study?**

During pregnancy, when you attend a clinic visit you will receive 20,000 pesos or a travel ticket to cover the cost of travel to the clinic, and if the time spent at the study visit extends through lunch, then you may be provided costs to cover a meal, 10,000-12,000 pesos.

**Will it cost me anything to be in this study?**

No. If you are part of this study, you and your baby will be tested for Zika virus. These tests will be paid for by the study. Any other tests conducted as part of the study will also be paid for by the study.

**Who should I call if I have questions about this study or think I may have gotten sick or been harmed by the study?**

If you have questions or think you or your baby have gotten sick or were harmed by the study, you should contact the Colombian study investigator. The study investigator's contact information is provided above.

**Who should I call if I have questions about my rights as a research volunteer?**

If you have any questions about your rights or your baby's rights as a participant in this study, please contact INS's [title] at [phone number]. Leave a message with your name, phone number, and refer to INS's Protocol # [Number], and someone will call you back.

**Do my baby or I have to be in this study?**

No. Being part of in this study is your decision. You or your baby may stop taking part in this study or certain parts of the study at any time. Your choice to join this study or to stop being part of the study will not affect your or your baby's ability to receive normal medical care.

**Subject's Agreement:**

Study ID \_\_\_\_\_

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

\_\_\_\_\_  
Signature of Research Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Subject

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

\_\_\_\_\_  
Date

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

## Sample Storage and Future Testing

Study ID \_\_\_\_\_

If you agree, samples of your body fluids or your baby's body fluids will be stored and may be used for things such as testing new methods for detecting Zika virus, evaluating the body's response to Zika infection, or for examining other factors that may impact pregnancy or newborn health. The information from testing these samples may be used for scientific research. These stored samples will only be labeled with your or your baby's participant identification number. No other information about you or your baby will be stored with the sample. The code linking the stored samples with you or your baby will still exist but will be kept separate from the samples.

You do not need to agree to store your or your baby's samples to take part in the study. If you agree for us to store these samples, we may keep them until they are used up or destroyed.

If you agree for us to store your samples, you may change your mind and decide not to allow us to store your samples. Please contact the study and ask that your samples be destroyed if you no longer agree to allow us to store your samples. The study's contact information is found at the beginning of this form.

### Your blood and urine samples:

\_\_\_\_\_ **I Agree** for any of **my** samples (blood, urine) to be stored and used for additional research purposes in the future.

\_\_\_\_\_ **I Do Not Agree** for any of **my** samples (blood, urine) to be stored and used for additional research purposes.

### Your amniotic fluid samples:

\_\_\_\_\_ **I Agree** for my **amniotic fluid samples** to be stored and used for additional research purposes in the future.

\_\_\_\_\_ **I Do Not Agree** for **my amniotic fluid samples** be stored and used for additional research purposes.

### Your baby's tissues:

\_\_\_\_\_ **I Agree** for any of **my baby's** tissues (from miscarriage, stillbirth, termination of pregnancy, or infant death) to be stored and used for additional research purposes in the future.

\_\_\_\_\_ **I Do Not Agree** for any of **my baby's** tissues (from miscarriage, stillbirth, termination of pregnancy, or infant death) to be stored and used for additional research purposes in the future.

### Your baby's blood and urine samples:

\_\_\_\_\_ **I Agree** for any of **my baby's** samples (blood, urine) to be stored and used for additional research purposes in the future.

\_\_\_\_\_ **I Do Not Agree** for any of **my baby's** samples (blood, urine) to be stored and used for additional research purposes.

Study ID \_\_\_\_\_

If we test your samples in the future and find a result that might affect your health or your baby's, would you like us to give the test result to you through your medical provider?

**Your samples:**

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

\_\_\_\_\_ **No**, I do not want the result.

**Your baby's samples:**

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

\_\_\_\_\_ **No**, I do not want the result.

\_\_\_\_\_  
Signature of Research Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Subject

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

\_\_\_\_\_  
Date

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

Participant is: Literate  Illiterate

Witness name, signature, and date are required on this form only when the participant is not able to read.

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

\_\_\_\_\_  
Date

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

**Contacting Research Subjects for Future Studies**

Study ID \_\_\_\_\_

Would you like the research staff to contact you about being a part of future research studies?

\_\_\_\_\_ **Yes**, I agree to be contacted

\_\_\_\_\_ **No**, I do not want to be contacted

\_\_\_\_\_  
Signature of Research Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Subject

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

\_\_\_\_\_  
Date

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

Participant is: Literate  Illiterate

Witness name, signature, and date are required on this form only when the participant is not able to read.

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

\_\_\_\_\_  
Date

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

**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

\_\_\_\_\_  
Signature of Research Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Subject

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

\_\_\_\_\_  
Date

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

Participant is: Literate  Illiterate

Witness name, signature, and date are required on this form only when the participant is not able to read.

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

\_\_\_\_\_  
Date

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

**Medical Records Release**

Study ID \_\_\_\_\_

As part of the ZEN study we would like to get a copy of your medical records so that we can know about your health during your pregnancy, and also about any medications you took during pregnancy and after. We would also like a copy of your baby’s medical records, to look for any health problems and to know about any medications.

We need your permission to look at your and your baby’s medical records. We are asking to access these medical records until the study is over. If we need to access the records after the study is over, 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.

We are required by law to maintain your and your baby’s information in strict confidence. Both the Instituto Nacional de Salud (INS, Colombia) and the Centers for Disease Control and Prevention (CDC, USA) have procedures in place to protect your privacy. But your privacy cannot be guaranteed.

You are not required to authorize the release of your or your baby’s medical records. It is your choice to agree or not. Your choice will not impact any services or benefits to which you are otherwise entitled. You will receive a copy of this form for your records.

The ZEN Colombia research study staff requests access to my and my baby’s medical records for research purposes. I have been told that this is voluntary, and that I may withdraw my authorization. I have been told that my privacy cannot be guaranteed.

- I authorize the release of **my** medical records to INS and CDC for the ZEN Colombia research study.
- I authorize the release of **my baby’s** medical records to INS and CDC for the ZEN Colombia research study.

\_\_\_\_\_  
Signature of Research Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Subject

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

\_\_\_\_\_  
Date

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

Participant is: Literate  Illiterate

Witness name, signature, and date are required on this form only when the participant is not able to read.

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

\_\_\_\_\_  
Date

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

**Signed copies of this medical records release form must be 1) retained on file by the principal study investigator, 2) given to the subject and 3) placed in the subjects medical records (when applicable).**