

Flesch-Kincaid Grade level: 7.7

Consent 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]

What I should know about this study?

We are asking you to take part in a research study because your partner is pregnant. 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 partner's medical 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 consent form. You should ask any questions you have about this study at any time.

Who is doing this study?

The 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 and to find out why some women and their partners get Zika virus. We will be testing the partners of pregnant women for Zika virus to better understand how Zika virus might be passed from men to women. We will also be looking at behaviors and health conditions that may predict why someone gets Zika virus.

How many people will be in this study?

The male partners of 5,000 pregnant women will be in this study.

How long will you need me?

The study will start in the first trimester of your partner's pregnancy and last until her baby is born.

During your partner's pregnancy:

- You will attend one study visit at the clinic that may take up to 60 minutes.

- Every month until around your partner’s 27th week of pregnancy, you will have an appointment with study staff at your home. These visits may 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. This visit may take up to 15 minutes.
- If you have Zika virus, you will be tested for Zika virus until the virus is gone from your body or the end of your partner’s pregnancy. These visits may take up to 15 minutes each.
- The results of tests conducted on you during the study that could affect your healthcare will be provided to you by your healthcare provider.

What do you want me 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)

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

- Review this informed consent form and ask any questions that you have about the study.
- Sign the consent form.
- Provide information about how the study staff can contact you.
- 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 take about 1 teaspoons of blood to test for 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 visits.

2. Home visits

Study staff will come to your home every month until around the start of your partner’s third trimester of pregnancy (about 27 weeks gestation). At these home visits you will do the following:

- Complete a questionnaire asking you about any Zika symptoms you have.
- Provide a sample of urine to the study staff. We will give you a sterile cup to collect a urine sample for Zika testing.

At the end of each home visit, we will schedule your next home visit.

3. Clinic visit if you have symptoms of Zika virus

If you call and report symptoms of Zika virus, we will ask you to schedule a clinic visit. At this visit, we will take a blood sample to test for Zika virus and ask you about symptoms of Zika virus.

4. Home visits if you have Zika virus

If you have Zika virus, we will ask you for a semen sample every two weeks until you do not have any Zika virus in your semen or until your partner’s pregnancy ends. We will give you a kit to collect this sample at home and your sample will be picked up by study staff during scheduled home visits.

Are there any risks to me if I decide to be in this study?

The risks of being part of this study are low:

- You might have some pain or bruising after we collect blood.
- You might get an infection after we collect blood. This is rare, and your chance of this happening is less than 1 in 1,000.
- Study staff will ask you questions about yourself and your 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 could be 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.

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

You will be tested for Zika virus more often than men who are not in this study, which means that you will be able to find out if you have Zika virus even if you do not have any symptoms. You might also indirectly benefit from new information about Zika virus that is found in this study.

What alternatives do I have to participating in this study?

You do not have to participate in this study. If you do not participate, your partner will continue to receive normal care during her pregnancy.

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 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 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 might develop an injury from being in this study. If these problems happen, the researchers will help you get medical care. Costs for your medical care will be covered by you or your insurance company. The study sponsor does not have any money set aside to cover your medical bills. By signing this form, you 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 can stop being in this study at any time.

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

Will I receive anything for being in this study?

During your partner's pregnancy, when you attend the enrollment 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 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 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 think you have questions or think you have gotten sick or 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 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 I have to be in this study?

No. Being part of this study is your decision. You 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 you or your partner's ability to receive normal medical care.

Subject's Agreement:

Study ID _____

By signing or making your mark on this consent 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 to participate in this study.

Signature of Research Subject

Date

Printed Name of Research Subject

Signature of Research Team Member Obtaining Consent

Date

Printed Name of Research Team Member Obtaining Consent

Participant is: Literate Illiterate

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

Signature of Witness

Date

Printed Name of Witness

Sample Storage and Future Testing

Study ID _____

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

You do not need to agree to store 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.

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

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

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

_____ **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 consenting 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 consenting participant is not able to read.

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