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. CDC

Funding Source: U.S. 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 the partners of pregnant women for Zika virus to better understand how Zika virus might be passed from men to women. We will also want to know how Zika infection during pregnancy can affect the health of the pregnant woman and the health of the baby.

How long will you need me?
The study will start in the first trimester of your partner's pregnancy. You are being asked to participate until the beginning of your partner's third trimester or if you become Zika positive, until your baby is born.

What do I have to do if I decide to participate in the study?
You will be asked to give a blood sample at enrollment to be tested for Zika virus. 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, we will ask you for a semen collection about every 2 weeks until you no longer have the Zika virus in your semen or until your partner's pregnancy ends. These samples and tests are in addition to testing that your health care provider may ask of you. You will be asked questions about your health and behaviors at enrollment and questions about Zika symptoms you may have at every study visit.

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

Are there any benefits if I accept to participate in the study?
You will be tested for Zika virus more often than men who are not in this study. You will have access to a team of professionals that will help support you and 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 share d with anyone outside of the investigation, 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 am injured by this study?

Problems may come up during any research as already mentioned. This can include risk of harm (for example hematomas 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 Rodriguez Parea at INS at 316 696 2942

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

Please contact Helena María Rodriguez Parea at INS at 316 696 2942. 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 medical care or benefits you, your partner, or your partner's baby would normally have.

Participant Consent: 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 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)

_____
Printed Name of Research Team Member Obtaining Consent

Sample Storage and Future Testing Study ID_____

If you agree, your samples of body fluids will be stored and can be used for future research related to Zika virus that is not currently a part of this study. At this point, we expect that 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 sample until it is used up or destroyed

You can change your mind and decide not to allow us to store your samples. If this occurs, we ask that you contact the study and ask that the samples be destroyed.

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

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

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?

_____ **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 **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 partner's pregnancy.

We need your permission to look at your 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.

Release of **your** 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

_____ _____
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