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:

<u>Introduction:</u> 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.

Appendix C3: ZEN Colombia Male Partner Consent – IRB approved on Jan 30, 2017 Last updated 03/02/17

Participant Consent:	Study ID
By signing or making your mark on this consent form, you agre someone read it to you, you had the chance to ask questions a 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 no	ot 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 Zika virus that is not currently a part of this study. At this point, we used to test new methods to detect Zika virus, to evaluate the beexamine factors that can affect pregnancy or the health of the new will not be stored with your sample. If we would like to use these specified above, we will contact you to get your permission.	ve expect that stored samples will be ody's response to Zika infection, or to ewborn. Other information about you
You do not need to agree with storing your samples to participate store the sample until it is used up or destroyed	te in the study. If you agree, we will
You can change your mind and decide not to allow us to store y that you contact the study and ask that the samples be destroyed	•
I agree for any of my samples (blood, urine or sen specified research purposes in the future.	nen) to be stored and used for the
I do not agree for any of my samples (blood, urine the specified research purposes in the future.	e or semen) to be stored and used for
If we test your samples in the future and find a result that might to give you the test result?	affect your health, would you like us
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

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Printed Name of Research Team Member

	Study ID
As part of the study we would like to get a copy of your medical your health during your partner's pregnancy.	records so that we can know about
We need your permission to look at your medical records. We a ecords until the study is over. If we need to access the records you to ask your permission. You are free to say no. You are als pefore the study is over.	after the study is over, we will contac
Release of your medical records:	
I agree to release my medical records for the res	earch 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)