ATTACHMENT 5
Consent Form and Assent Form

Consent Form

Hello. My name is _ _ _ _ _ _ _ _ _ _ _ _ _, and am responsible researcher or research team of professional Ministry of health of Brazil and the Centers for disease control and prevention of the United States of America (USA).

You are being invited to volunteer to participate in the survey "research on the outcomes of Zika and development in infants and children (ZODIAC)", developed by the Secretariat of health surveillance, Ministry of health of Brazil, and by the Centers for disease control and prevention of the United States of America. The research aims to improve our knowledge about changes in health and development outcomes of children of 12 to 24 months with congenital infection by the virus Zika (ZIKV). The Zika virus is transmitted to people by mosquitoes. Most people infected by the virus Zika doesn't get sick and only a fifth of them showing symptoms. The most common symptoms of Zika virus infection are rashes, fever, joint pain and eye redness. Other symptoms may include headache or muscle aches. It was found that some babies in Brazil who were born with a small head (microcephaly) were infected by the virus Zika. It is possible that these children have been infected when your mother was bitten by a mosquito with the Zika virus during pregnancy. We are looking for children infected during pregnancy, so that they can participate in the investigation along with their mother or other person responsible for their care and help us learn more about the infection by Zika. The results will help the Ministry of health and State your understand better the services your family needs.

In this research, our goal is to describe the State of health and development, as well as the medical and social needs of children between 12 and 24 months, with congenital infection confirmed, probable or no evidence of congenital infection by the virus Zika, in the States of Paraíba and Ceará. In addition, it will be described the relationship between the presence of a child with congenital infection by ZIKV and the well-being of the mother or other person responsible for taking care of the child, as well as a reflection of this situation on family health.

So, if you agree, we'd like to ask you some questions about you, your family, and your baby. These questions will be made by skilled health professionals using questionnaires containing questions about your health since the baby was born,, the health of your baby from birth to the present day, and also questions related to your family. We would also like to examine your baby to see how he/she's going through. We measure the size and the length of the head him/her and perform some physical assessments (for example: test of vision, hearing) and motor (for example, physical examination, examination of reflexes). The doctors examining your baby will provide a summary of what they find during these assessments.

We also ask your permission to collect information from your and your baby's medical records. If you and your child participated in a previous investigation conducted in 2016, we are also ask for your permission to use the information gathered during that investigation. Finally, we would like to take some of your baby's blood in the veins of the arm. To collect the blood, a professional lab (phlebotomist), wearing gloves, disposable needle and syringe, stick in your baby's little arm. We would need more or less half a teaspoon (3 ml) of blood. We're going to need you and your baby for about 2 to 4 hours, distributed in one or more meetings. These meetings will take place in your State health establishments previously identified in the survey and that is convenient for you and your baby.

The blood collected will be analyzed both in laboratories in Brazil, as indicated by the Ministry of health, as the United States of America, in the laboratories of the Centers for disease control and prevention (CDC). The blood sample will be examined to verify the possibility of Zika virus infection. Will be also examined other factors associated with the development, as the level of lead and thyroid hormones, as well as hepatic and renal

function. After the tests, the blood sample is destroyed. The blood of your child will be used exclusively for purposes connected to the Zika virus.

The information you provide as well as the information that the researchers will collect from examining your baby will help us learn more about Zika virus affects children's development and the family.

We will do everything possible so that data that permit the identification of the research participant are kept confidential in order to protect the privacy and confidentiality of research participants at all stages of the research, causing no damage, such as stigma and discrimination. We're not going to use your baby's blood samples for future testing, or genetic tests, such as DNA or HIV testing.

There may be small discomforts and risks related to blood collection by venipuncture, i.e. vein blood collection. Between these discomforts are bearable pain at the site of the sting of the needle and emergence of purple stain (bruise) on the site. Fainting may occur rarely, mostly of people who have a phobia for blood, and infection at the site of the sting. If an emergency develops, it will be addressed in accordance with clinic procedures.

It is possible that we make recommendations of other tests to your child, depending on the results of the tests. If this happens, you will be advised to take your child to your regular doctor or another health service to do any tests or additional examination. We ask your permission for your doctor or health service to share the results of these tests or examinations with our research team. The research will bear the costs of these tests or additional charges.

All the information you provide us will be confidential, and only researchers working on this investigation will have access to them. But there is a small risk that others can have access to your information. The research reports will be in the form of abstracts, so that no information that could identify you personally will be shared with other people. The answer to the questions is completely voluntary, and you can stop the interview at any time you want, or you can tell it not to answer any specific question. The same applies to blood samples. You are guaranteed full freedom of refusing to participate in the research or withdraw your consent at any stage of the survey, without any type of injury or penalty.

We may have more questions about your illness or your current state of health in the future. In this case, we would request permission to return to contact you at some point in the future to do some more questions If you don't want to, we're not going to make contact again.

The research will have no cost to the participants. Expenditure relating to procedures and examinations provided for in the research are all paid by the sponsoring institution. If you or your companions have some expense to participate in the research, such as transport and food, responsible for research institutions undertake to fully indemnify these costs.

In case of any doubt as to the ethical conduct of the study, contact the National Commission of ethics in research (CONEP), which defends the interests of research participants in your integrity and dignity and ensures the development of research in ethical standards. In this way the CONEP has the role to evaluate and monitor the progress of the project so that the research meets the ethical principles of protection of human rights, dignity, autonomy, non-maleficence, confidentiality and privacy.

The research group presents a policy of providing timely information, in case of doubts arising from the end of the survey, or their families, emphasizing the importance of avoiding distress or excessive concern with the results.

Seguem os contatos da Comissão Nacional de Ética em Pesquisa (CONEP):

Tel: (61) 3315-5878 / (61) 3315-5879

e-mail: conep@saude.gov.br

You can also contact one of the researchers responsible for the research in the Ministry of health, das 09h00 à 18h00: Isabela Ornelas Pereira
Tel (0XX) 61- 3213-8034/8004
e-mail: isabela.opereira@saude.gov.br
Coordenação Geral dos Programas Nacionais de Controle e Prevenção da Malária e das Doenças Transmitidas pelo Aedes (CGPNCMD)
Endereço: SRTV 702, Via W 5 Norte, Unidade VI do Ministério da Saúde, Edifício PO 700, 6° andar.

This term is drawn up in two copies, one for the participant and one for the researcher. All pages must be initialled by the end of the search and the responsible researcher (or a person delegated by him, and under your responsibility), with both signatures on the last page.

Do you have any questions?

Field Researcher name: _____

Signature of the field Researcher: _____

Date: ____/_____/_____

Select/Select aspects of this investigation with which you agree:

( ) Accepted answer questions and agree with physical examination of my child and collection of blood from my child.

( ) I agree to allow the analysis of my medical charts of any medical queries about my health or the health of my child because of illness since 1st January 2015.

( ) Participated in the control case study conducted in the State of Paraíba, in 2016, and I authorize the use of my data and that of my child for this research.

( ) I agree to be contacted in the future.

I would like the results of examinations performed for this research to be sent to:

( ) Me directly via postal mail

( ) My health care provider.

Name of the provider of health services: _____

Address or name of the establishment: _____

Name of the Responsible legal: _____

Signature of legal guardian: _____

Date: _____/_____/_____

Assent Form

Hello. My name is _ _ _ _ _ _ _ _ _ _ _ _ _, and am responsible researcher or research team of professional Ministry of health of Brazil and the Centers for disease control and prevention of the United States of America (USA).

You are being invited to volunteer to participate in the survey "research on the outcomes of Zika and development in infants and children (ZODIAC)", developed by the Secretariat of surveillance of Brazil's Ministry of health and the Centers for disease control and prevention of the United States of America. The research aims to improve our knowledge about changes in health and development outcomes of children of 12 to 24 months with congenital infection by the virus Zika (ZIKV). The Zika virus is transmitted to people by mosquitoes. Most people infected by the virus Zika doesn't get sick and only a fifth of them showing symptoms. The most common symptoms of Zika virus infection are rashes, fever, joint pain and eye redness. Other symptoms may include headache or muscle aches. It was found that some babies in Brazil who were born with a small head (microcephaly) were infected by the virus Zika. It is possible that these children have been infected when your mother was bitten by a mosquito with the Zika virus during pregnancy. We are looking for children infected during pregnancy, so that they can participate in the investigation along with their mother or other person responsible for their care and help us learn more about the infection by Zika. The results will help the Ministry of health and State your understand better the services your family needs.

In this research, our goal is to describe the State of health and development, as well as the medical and social needs of children between 12 and 24 months, with congenital infection confirmed, probable or no evidence of congenital infection by the virus Zika, in the States of Paraíba and Ceará. In addition, it will be described the relationship between the presence of a child with congenital infection by ZIKV and the well-being of the mother or other person responsble for taking care o fhe child, as well as a reflection of this situation on family health.

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We will also like to collect information from your and your baby’s medical records. If you and your child participated in a previous investigation conducted in 2016, we are also ask for your permission to use the information gathered during that investigation.

Finally, we would like to take some of your baby's blood in the veins of the arm. To collect the blood, a professional lab (phlebotomist), wearing gloves, disposable needle and syringe, stick in your baby's little arm. We would need more or less half a teaspoon (3 ml) of blood. We're going to need you and your baby for about 2 to 4 hours, distributed in one or more meetings. These meetings will take place in your State health establishments previously identified in the survey and that is convenient for you and your baby.

We're also going to ask your parent or guardian if he or she agrees with your participation in the research. You will participate only if both you and your parent or guardian agree with your participation and sign an authorization. All right for you?

The blood collected will be analyzed both in laboratories in Brazil, as indicated by the Ministry of health, as the United States of America, in the laboratories of the Centers for disease control and prevention (CDC). The blood

sample will be examined to verify the possibility of Zika virus infection. Will be also examined other factors associated with the development, as the level of lead and thyroid hormones, as well as hepatic and renal function. After the tests, the blood sample is destroyed. The blood of your child will be used exclusively for purposes connected to the Zika virus.

The information you provide as well as the information that the researchers will collect from examining your baby will help us learn more about Zika virus affects children's development and the family.

We're not going to use your baby's blood samples for future testing, or genetic tests, such as DNA or HIV testing.

There may be small discomforts and risks related to blood collection by venipuncture, i.e. vein blood collection. Between these discomforts are bearable pain at the site of the sting of the needle and emergence of purple stain (bruise) on the site. Fainting may occur rarely, mostly of people who have a phobia for blood, and infection at the site of the sting. If an emergency develops, it will be addressed in accordance with clinic procedures.

It is possible that we make recommendations of other tests to your child, depending on the results of the tests. If this happens, you will be advised to take your child to your regular doctor or another health service to do any tests or additional examination. We ask your permission for your doctor or health service to share the results of these tests or examinations with our research team. The research will bear the costs of these tests or additional charges.

All the information that you provide will be confidential, that is, will not be passed on to anyone. Only the researchers of this investigation will be able to see them.
The answer to the questions is completely voluntary, and you can say you don't want to answer at any time during the interview. You also don't have to answer all the questions, you can answer only those you want. At any time you can say you don't want to participate in the research, and there will be no problem with that.

We may have more questions about your illness or your current state of health in the future. In this case, we would request permission to return to contact you at some point in the future to do some more questions If you don't want to, we're not going to make contact again.

The research will have no cost to the participants. Expenditure relating to procedures and examinations provided for in the research are all paid by the sponsoring institution. If you or your companions have some expense to participate in the research, such as transport and food, responsible for research institutions undertake to fully indemnify these costs.

If you want to talk to someone about this research, you can contact the National Commission of ethics in research (CONEP), in Brasilia, by phone or email. The CONEP ensures that this research does not cause you any problem and will always protect your rights and your interests. The telephone and the e-mail address of CONEP are below.
Tel: (61) 3315-5878 / (61) 3315-5879
e-mail: conep@saude.gov.br

You can also contact the responsible researcher at the Ministry of health, Monday to Friday, from 9:00 to 6:00 pm:

Isabela Ornelas Pereira

Tel (0XX) 61- 3213-8004/8006
e-mail: isabela.opereira@saude.gov.br
Coordenação Geral dos Programas Nacionais de Controle e Prevenção da Malária e das Doenças Transmitidas pelo Aedes (CGPNCMD).
Endereço: SRTV 702, Via W 5 Norte, Unidade VI do Ministério da Saúde, Edifício PO 700, 6° andar.

By signing or making a mark on this consent form, you accept that you have read or that another person has read the form to you, that you have had the opportunity to ask questions about everything you did not understand, and that you voluntarily agree to participate in this study.

Select/Select aspects of this investigation with which you agree:
( ) Accepted answer questions and agree with physical examination of my child and collection of blood from my child.
( ) I agree to allow the analysis of my medical charts of any medical queries about my health or the health of my child because of illness since 1st January 2015.
( ) Participated in the control case study conducted in the State of Paraíba, in 2016, and I authorize the use of my data and that of my child for this research.
( ) I agree to be contacted in the future.

I would like the results of examinations performed for this research to be sent to:
( ) Me directly via postal mail
( ) My health care provider.
Name of the provider of health services: _____
Address or name of the establishment: _____

We will sign this term in two ways: one is with you and other with me. If you have any questions before you sign, I'm here to answer them. And thank you very much for helping us with this research.

Field Researcher name: _____ Date: ____/_____/_____

Signature of Field Researcher: _____

Name of participant 12- 18 years old (print):

_____ Date: ____/____/_____

Name of person providing consent for participant 12-18 years old (print):

_____ Date: ____/____/_____

Signature of person providing consent for participant 12-18 years old:

_____

Person signing above is:
☐ Parent
☐ Legal guardian