Form Approved
OMB No. 0920-0010
Exp. XX/XX/XXXX

Verbal Informed Consent for Release of Reportable Infectious Diseases Results

During your phone interview you gave us some information about your past pregnancy to help us better understand some of the causes of birth defects. You helped us learn a lot about this topic, but there is still a lot to study about pregnancies affected by birth defects as well as pregnancies not affected by birth defects, some of which may have ended in a stillbirth. To further help us understand the impact of infectious diseases during pregnancy, we will be collecting information on infectious diseases before and during pregnancy that were reported by your doctor to your state health department. If you did not report a previous infectious disease during the telephone interview, the results will tell us if your doctor reported a test result from an infectious disease from two years before your pregnancy through the end of your pregnancy <<[**For Centers**,] specifically, the following reportable conditions: Chikungunya, Chlamydia, Dengue fever, Gonorrhea, Hepatitis A B or C, Lyme disease, Malaria, Novel Influenza A virus, West Nile virus, Zika virus and HIV.>>

The <**State Health Department/Agency**> collects information directly from doctors on nationally reportable infectious diseases in <**INSERT STATE**> to monitor, control, and prevent infectious diseases and their spread. This information has already been collected and no additional data collection is needed. The information provided will be used to study how maternal infectious diseases may play a role in why some pregnancies are affected by birth defects and other pregnancy problems. Your infectious disease information will only be used to study birth defects and other pregnancy problems and for no other purpose.

Your data will be stored in an electronic format with a code number that does not contain any information that could identify you with your infectious disease information. A researcher who wants to study your infectious disease information must apply to use the data. Only researchers who have a study about birth defects or other pregnancy problems that is approved by a human subjects review committee and an agreement to use the data for research on birth defects or other pregnancy problems will be allowed to see and use your infectious disease information. Researchers who are given access to the data must use appropriate security measures to protect your identity.

There is no additional risk to you because the information has already been collected by the <**INSERT STATE**> as part of the National Electronic Disease Surveillance System.

There is no personal benefit to you for taking part in this study. Your records may contribute to the understanding of how infectious diseases may cause birth defects or other pregnancy problems. The major benefit is that this study may result in a better understanding of the causes of birth defects and other pregnancy problems. We will share what we learn with other health professionals through medical publications. None of these publications will include information that could identify you in any way.

All information that we gather in this study will be kept confidential. This is assured by a Certificate of Confidentiality that protects your legal rights under the Public Health Service Act *(under section 301[d] of the Public Service Act 42 U.S.C. 241[d])*. The Certificate of Confidentiality prevents study staff from being forced under a court order or other legal action to identify your child or anyone else in this study. This protection lasts forever (even after death) for any persons who were subjects in the research during any time the Certificate was in effect. However, you should understand that the researchers are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others. Records may be reviewed by officials checking on the quality of the research. Information obtained from you may be shared with researchers when and if it has been approved by human research subject review committee. Researchers will never use any names in reports or publications.

After we receive the signed consent form, we will send you a $10 gift card as a token of appreciation for your time and interest. There is no cost to you in order to participate in the reportable infectious disease portion of the study.

Participation in all parts of this study is voluntary. You are free not to take part in the study and you are free to withdraw from any or all parts of this study at any time without penalty or loss of benefits to you. You may request to have your infectious disease information and interview data removed from the study at any time. After receiving this request, we will remove your infectious disease information and interview data from all future studies.

The **<State Health Department/Agency>** has agreed to provide infectious disease information for selected infections two years before and during pregnancy with your permission. The information provided will be used to study how maternal infectious diseases may play a role in why some pregnancies are affected by birth defects and other pregnancy problems. Your infectious disease information will only be used to study birth defects and other pregnancy problems and for no other purpose.

We are asking for permission to submit your name to the **<State Health Department/Agency>**'s infectious disease monitoring program to obtain information on reportable infectious diseases that you may have had in the two years before your pregnancy or during your pregnancy.

Your infectious disease information will not be used for commercial purposes.

Do you have any questions?

[If the parent has questions about the Reportable non-HIV Infectious Diseases Results, provide the contact information for the CDC: If you have questions about your rights, as a subject in this research study, please call <<the Office of the Deputy Associate Director for

Science for CDC at 1-800-584-8814, leave a message including your name, phone number, and refer to protocol #2087, and someone will call you back as soon as possible.>> OR << insert local IRB contact if not deferring.>>]

If not, I am going to read the consent to you. This consent is for:

Mother's name: _____

I give permission to submit my name to the <State Health Department/Agency>'s infectious disease monitoring program to obtain information on reportable infectious diseases <<[For Centers,] for Chikungunya, Chlamydia, Dengue fever, Gonorrhea, Hepatitis A B or C, Lyme disease, Malaria, Novel Influenza A virus, West Nile virus, Zika virus, and HIV.>> that I may have had in the two years before my pregnancy and during my pregnancy. This information has already been collected and no additional data collection is needed.

I have read this consent form or had its contents explained to me.
All of my questions have been satisfactorily answered.

Do you wish to give your consent?
__Yes __No

Interviewer's signature: _____ Date: _____

Print interviewer's name: _____