

Verbal Informed Consent for Release of Reportable Infectious Diseases Results

To better 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, HIV, and Coronavirus or COVID-19.>>

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.

<All except CA: 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.>

<CA Only: There is additional, though minimal, risk of possible loss of confidentiality upon data transfer to <State Health Department/Agency>.>

<**For CA and NY:** If you agree to participate in this part of the study, 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. >

<**For AR:** If you agree to participate in this part of the study, we will load your ClinCard with \$10 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. >

There is no personal benefit to you for taking part in this study; participation is voluntary. You are free to withdraw from any or all parts of this study at any time without penalty. You may request to have your infectious disease information and interview data removed from the study at Public reporting burden of this collection of information is estimated to average 15 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0010).

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.

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.

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, HIV, and Coronavirus or COVID-19.>> 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: _____

