Form Approved
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# Informed Consent for Release of Reportable Infectious Diseases Results

**TITLE OF STUDY**: Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS

## RESEARCHERS:

National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, and the Centers for Birth Defects Research and Prevention in Arkansas, California, Iowa, Massachusetts, New York and North Carolina.

## PURPOSE OF STUDIES USING REPORTABLE INFECTIOUS DISEASE INFORMATION:

Major birth defects occur in about three out of every 100 babies. The cause of the birth defect is unknown for most of these babies. Birth defects can be prevented only if these causes are understood. Researchers are working with the Centers for Disease Control and Prevention (CDC) to study pregnancies affected by birth defects as well as pregnancies not affected by birth defects, some of which may have ended in a stillbirth. You have already provided us with information through a telephone interview to help us to understand causes of birth defects and other pregnancy problems. 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, 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. 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.

## PROCEDURES FOR RELEASE OF REPORTABLE INFECTIOUS DISEASE INFORMATION:

If you decide to participate in this part of the study, we would like to have your permission to request your infectious disease information that was already reported by your doctor to the

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).

<**INSERT State Health Department/Agency**>. This information has already been collected and no additional data collection is needed. 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.

## SHARING YOUR REPORTABLE INFECTIOUS DISEASE INFORMATION:

<<All except CA: To do more meaningful research, it is helpful for researchers to explore as many sources of information they can to better study maternal infectious diseases.>>
<<MA Only: Any information obtained by the Massachusetts Department of Public Health on reportable infectious diseases, specifically about 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 you may have had in the two years before your pregnancy or during your pregnancy) will be shared with the National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, and the Centers for Birth Defects Research and Prevention in Arkansas, California, Iowa, Massachusetts, New York and North Carolina.>>
<<CA Only: There is additional, though minimal, risk of possible loss of confidentiality upon data transfer to <State Health Department/Agency>.>>

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.

## RISKS OF SHARING REPORTABLE INFECTIOUS DISEASE INFORMATION:

<<All except MA: 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.>>
<<MA Only: Although your reportable infectious disease information has already been reported to the Massachusetts Department of Public Health as required by law, there may be some small additional risk to your personal information by participating in this study since your information will be shared with the National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, and the Centers for Birth Defects Research and Prevention in Arkansas, California, Iowa, Massachusetts, New York and North Carolina. However, your information will be stored and shared with other researchers in an electronic format with a code number that does not contain any information that could readily identify you.>>

## BENEFITS OF SHARING REPORTABLE INFECTIOUS DISEASE INFORMATION:

There is no personal benefit to you for taking part in this study. 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.

## CONFIDENTIALITY:

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.

## COSTS/COMPENSATION:

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. Your records may contribute to the understanding of how infectious diseases may cause birth defects or other pregnancy problems.

## RIGHT TO REFUSE OR WITHDRAW:

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.

## COMMERCIAL VALUE OF INECTIOUS DISEASE REPORTING:

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

**If you have any questions, please contact:**
**1-888-743-7324 or questions@bdsteps.org**

**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.>>**

**BD-STEPS PARTICIPANT CONSENT**:

**I give permission for my information to be submitted to the <State Health Department/Agency> infectious disease monitoring program <<[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>>. Please print all names you may have used up to two years before your pregnancy and sign below.**

**Print name: ________________________________________________**

**Other names: ________________________________________________**
(Other names include your maiden name, professional name, or any other name by which you are or have been known)

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

Signature: ______________________________ Date: _________________________

<<**INCLUDE IF SENDING FOR IDENTIFIED MINOR IN STATES WITH MINOR RESTRICTIONS (CA, NC AND AR**):

Parent/Legal Guardian's signature of mother, if mother is a minor
Signature:___________________________________ Date: _________________________

Print Name of Parent/Legal Guardian of mother:___________________________________>>

## <<AR Only: RELEASE OF REPORTABLE HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFORMATION:

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. This release is specifically consenting for the <State Health Department/Agency> to provide HIV reported information. If you decide to participate in this part of the study, we would like to have your permission to request your infectious disease information for HIV that was already reported by your doctor to the <INSERT State Health Department/Agency>. The HIV information has already been collected and no additional data collection is needed. The **<State Health Department/Agency>** has agreed to provide HIV information for 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 HIV information will only be used to study birth defects and other pregnancy problems and for no other purpose. Your HIV 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 HIV 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 HIV 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 HIV eHARS registry. There is no personal benefit to you for taking part in this study. 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.

**BD-STEPS PARTICIPANT CONSENT**:

**I give permission for my information to be submitted to the <State Health Department/Agency> infectious disease HIV monitoring program. Please print all names you may have used up to two years before your pregnancy and sign below.**

**Print name: ______________________________________________**

**Other names: ______________________________________________**
(Other names include your maiden name, professional name, or any other name by which you are or have been known)

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

Signature: ____________________________ Date: ___________>>

<<**INCLUDE IF SENDING FOR IDENTIFIED MINOR IN STATES WITH MINOR RESTRICTIONS (CA, NC AND AR**):

Parent/Legal Guardian’s signature of mother, if mother is a minor
Signature:_________________________________ Date:________________________

Print Name of Parent/Legal Guardian of mother:________________________________>>