

Written Informed Consent

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 BIOLOGIC SAMPLE COLLECTION:

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 babies who do and do not have birth defects to try to understand their causes. To help us to understand environmental and other causes of birth defects, you have already provided us with information through a telephone interview. To help us understand more about how genes or our genetics may play a role in birth defects, we are also collecting biologic samples.

BIOLOGIC SAMPLE COLLECTION PROCEDURES:

If you decide to take part in this study, we would like you to give us saliva samples from yourself, your child, and your child's father. Saliva samples are collected from your child by rubbing the inside of the cheek with soft sponges. Saliva samples are collected from each parent by spitting into a funnel connected to a small collection tube. These samples will be used to study genes, which may play a role in why some babies have birth defects. They will only be used to study birth defects and for no other purpose. We have no plans to ever destroy these samples.

We would also like to have your permission to request a newborn blood spot that was already collected from your baby shortly after birth by the <INSERT State Lab.> The state lab collects a few drops of blood onto a card from every baby born in <INSERT STATE> to check for certain rare inherited conditions. They usually have leftover blood spots. The state lab has agreed to let us have a leftover blood spot from your baby if we have your permission.>>

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).

BIOLOGIC SAMPLE COLLECTION RISKS:

The possible physical risk of this procedure is temporary, minor discomfort to the inside of the mouth when using sponges. To protect your confidentiality, no names or other personal information will be attached to the biologic samples. Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small and we have many safeguards in place to keep your information confidential.

BENEFITS OF BIOLOGIC SAMPLE COLLECTION:

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. We will share what we learn with other health professionals through medical publications. None of these publications will include information that could identify you, your child's father or your child 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 you 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 investigators 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 about you may be shared with other researchers when and if it has been approved by research review committees. We will never use any names in reports or publications. Genetic data will be used only for the study of birth defects. You may request a copy of the Certificate of Confidentiality for this study at any time.

COSTS/COMPENSATION:

Parents who agree to provide saliva samples on themselves and their child will receive a \$20 gift card per family with the kit as a token of appreciation for your time and interest. Each family will receive an additional \$20 gift card when the kit is returned. CDC does not normally pay for medical treatment in the unlikely event of injury as a result of taking part in this study.

RIGHT TO REFUSE OR WITHDRAW:

Participation in all parts of this study is voluntary. You are free to not 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. In addition, when your child reaches the age of 18 and after this, he or she can also contact the study and withdraw. You may request to have your interview information or biologic samples destroyed or removed from the study at any time. Although we will not use data from the withdrawn samples in the future, we cannot remove the sample data from findings or articles that have already been published.

LABORATORY RESULTS:

The studies that will be done on these samples are not meant to test the medical status of you, your child, or your child's father. Since all studies will be done in research labs, we do not plan

to return the results of the studies to you. Research labs do not have the same quality control standards as clinical labs, which can make the tests less reliable than those from a clinical lab. However, a few of these studies may have clinical importance. For any tests that have clinical importance, we will publish summarized results in the study newsletter. This newsletter is available to all participants when it is published on line each year at www.bdsteps.org. If you have questions about whether any genetic tests would be useful to you, we recommend that you consult your health care provider.

CONTROL and OWNERSHIP OF BIOLOGIC MATERIALS:

Some of the biologic samples will be studied shortly after they are collected. Most of the saliva samples will be stored in a specimen bank for studies in the future. Study researchers will have control over the stored samples unless you request that your sample be removed from storage.

COMMERCIAL VALUE OF BIOLOGIC MATERIALS:

We will not use the biologic samples collected from you for commercial purposes.

SHARING YOUR GENETIC AND HEALTH INFORMATION FOR FUTURE RESEARCH:

To do more powerful research, it is helpful for researchers to share information they get from studying genetic samples. Your genetic and health information might be placed into one or more centralized scientific databases. Sharing your genetic and health information will allow it to be combined with information from other studies so that researchers can learn even more about children's health and birth defects. Your names will not be included in the databases. A researcher who wants to study the information must apply to get access to your data. Only researchers who have certified agreements to use the data for research that is consistent with BD-STEPS informed consents will be allowed to see and use your information. Researchers who are given access to the data will be agreeing to use appropriate security measures.

If you have any questions, please contact:

1-888-743-7324 or BD-STEPS@abtassoc.com

<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.

PARTICIPANT CONSENT:

Print infant's name: _____

If a sample is being sent from your child, please sign below (either parent may sign):

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

9999999999999999

Parent's signature: _____ Date: _____

If a sample is being sent from the mother, please sign below:

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

8888888888888888

Mother's signature: _____

Print mother's name: _____ Date: _____

<Signature of parent/legal guardian of mother if mother is a minor (non-emancipated):

_____>

If a sample is being sent from the father, please sign below:

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

7777777777777777

Father's signature: _____

Print father's name: _____ Date: _____

<Signature of parent/legal guardian of father if father is a minor (non-emancipated):

_____>

<<If I am giving permission for my child's leftover newborn blood spot to be requested from the <State Laboratory>, please sign below (either parent may sign). These samples already exist and no additional collection is needed.

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

Parent's signature: _____ Date: _____