

Informed Consent for Newborn Bloodspots

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 participate in this part of the study, we would like to have your permission to request some of the leftover heel stick blood 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 the heel of every baby born in <INSERT STATE> to check for certain rare inherited conditions. They usually have leftover bloodspots on these cards. The state lab has agreed to let us have some of the leftover heel stick blood from your baby if we have your permission. These samples will be used to study genes and other biologic factors, 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.

BIOLOGIC SAMPLE COLLECTION RISKS:

There is no physical risk because the bloodspots have already been collected from your child shortly after birth. To protect your child's confidentiality, no names or other personal

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).

information will be attached to the biologic samples. Because genetic information is unique to each person, there is a small chance that someone could trace it back to your child. The risk of this happening is very small and we have many safeguards in place to keep your child's information confidential.

BENEFITS OF BIOLOGIC SAMPLE COLLECTION:

There is no personal benefit to your child 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 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 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 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:

We have included a \$10 gift card as a token of appreciation for your time and interest.

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, he or she can also contact the study and withdraw. You may request to have your interview information or your child's biologic samples destroyed or removed from the study at any time. If you request that samples be destroyed, we will not use data from the withdrawn samples in the future, but we cannot remove the sample data from articles that have already been published.

LABORATORY RESULTS:

The BD-STEPS studies that will be done on the bloodspots are not meant to test the medical status of your child. The research labs we use in BD-STEPS do not have the same quality control

standards as clinical labs, which can make the tests less reliable than those from a clinical lab. Since all BD-STEPS studies will be done in research labs, we do not plan to return the results of these studies to you. However, a few of the BD-STEPS 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 online each year at www.bdsteps.org. If you have questions about whether any genetic tests would be useful to you or your child, we recommend that you consult your health care provider.

CONTROL and OWNERSHIP OF BIOLOGIC MATERIALS:

The leftover newborn bloodspot samples that are shared with our study will either be studied shortly after they are received or will be stored for studies in the future. <<Study researchers will have control over the stored samples unless you request that your child’s sample be removed from storage.>> OR <<The samples will remain under the ownership of the <insert health department name.>>>

COMMERCIAL VALUE OF BIOLOGIC MATERIALS:

We will not use the biologic samples collected from your child 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 child’s genetic and health information might be placed into one or more centralized scientific databases. Sharing your child’s 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 questions@BD-STEPS.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.>>

PARTICIPANT CONSENT:

Print infant's name: _____

I give permission for my child's leftover newborn bloodspots 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: _____

Print parent's name: _____