Informed Consent for Release of Leftover 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 STUDIES USING NEWBORN BLOODSPOTS:
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 and other biologic factors may play a role in birth defects, we also plan to do studies that use leftover newborn bloodspots.

PROCEDURES FOR RELEASE OF LEFTOVER NEWBORN BLOODSPOTS:
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 (also called a newborn bloodspot) that was already collected from your baby shortly after birth by the <**INSERT State Lab or other collection agency**>. The **<state lab or other collection agency>** 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 newborn bloodspots on these cards. The **<state lab or other collection agency>**has agreed to let us have some of the leftover newborn bloodspots 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. <NC only: If you would like to participate in this part of the study, we request that you review and sign this Consent Form from the Birth Defects Study to Evaluate Pregnancy exposureS (BD-STEPS) , and review and sign the attached Authorization Form from the NC State Laboratory of Public Health.>

SHARING YOUR CHILD'S NEWBORN BLOODSPOT DATA FOR FUTURE RESEARCH:

To do more powerful research, it is helpful for researchers to share information they get from studying newborn bloodspots. Your child's newborn bloodspot data and some limited other information (such as your child's race, ethnic group, and birth defect type) might be placed into one or more centralized scientific databases (such as National Institutes of Health databases). Sharing this information will allow it to be combined with information from other studies so that researchers can learn even more about birth defects. Your child's name will not be included in the databases. The other information included, such as your child's race and ethnic group, helps researchers learn whether the factors that lead to birth defects are the same in different groups of people. It is possible that such findings could one day help prevent birth defects. However, results reported by group, such as race or ethnicity, could cause distress to group members.

The data will be stored in an electronic format with a code number that does not contain any information that could identify your child. A researcher who wants to study your child's data must apply for access to the data. Only researchers who have a birth defects study that is approved by a human subjects review committee and a certified agreement to use the data for birth defects research will be allowed to see and use your child's information. Researchers who are given access to the data will be agreeing to use appropriate security measures.

RISKS OF SHARING LEFTOVER NEWBORN BLOODSPOTS:
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 information will be attached to the newborn bloodspot samples. The sample data will be stored in electronic format with a code number that does not contain any information that could identify your child. Because genetic information is unique to each person, there is a small chance that someone could trace it back to your child if they have another source of your child's genetic information. Although genetic information is unique to each person, each person shares some genetic information with their blood relatives. As a result, it may be possible that genetic information from blood relatives could be used to help identify your child. Similarly, it may be possible that genetic information from your child could be used to help identify blood relatives. There is also a chance your child's information could be improperly released. The risk of this happening is very small and we have many safeguards in place to keep your child's information confidential. Additionally, there are state and federal laws that protect against genetic discrimination.

BENEFITS OF SHARING LEFTOVER NEWBORN BLOODSPOTS:
There is no personal benefit to you or 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 you 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 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 committees. Researchers will never use any names in reports or publications. Genetic data will be used only for the study of birth defects.

COSTS/COMPENSATION:
After we receive the signed consent form <NC only: and authorization form>, we will send you a $10 gift card to compensate you 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. You may request to have your child's newborn bloodspot samples, the sample data, and the interview data removed from the study at any time. In addition, when your child reaches the age of 18, he or she can also contact the study and request to withdraw. After receiving this request, we will remove your child's newborn bloodspot samples and sample data from all future studies. However, we cannot remove newborn bloodspot samples and sample data from studies that started before the request was received.

LABORATORY RESULTS:
The BD-STEPS studies that will be done on the leftover newborn 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 will not return your child's individual results. 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 NEWBORN BLOODSPOT SAMPLES:
The leftover newborn bloodspot samples that are shared with BD-STEPS will be studied by birth defects researchers when and if a proposed study has been approved by a human subjects review committee. The samples will be studied shortly after they are received or will be stored for studies in the future. <BD-STEPS researchers> OR <insert local Center researchers> will have control over the stored samples after they are received from < insert health department name > unless you request that your child's sample be removed from <BD-STEPS> storage. The samples will remain under the ownership of the <insert health department name> until they are requested by BD-STEPS researchers.

COMMERCIAL VALUE OF NEWBORN BLOODSPOT SAMPLES:
Your child's newborn bloodspot samples or newborn bloodspot data 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 child's 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 child's name: _____

I give permission for my child's leftover newborn bloodspots to be requested from the <State Laboratory or other collection agency>. Please sign below (either parent may sign). These samples have already been collected 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:_____

<<**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:_____>>

<<NY ONLY:
I agree to indefinite storage of my child's sample.

Parent's signature: _____ Date: _____

Print parent's name:_____>>