Form Approved
OMB No. 0920-0010
Exp. XX/XX/XXXX

Verbal Informed Consent for Release of Leftover Newborn Bloodspots
For Mothers of Multiples (e.g. Twins and Triplets)

During your phone interview you gave us some information about your past pregnancy to help us better understand some of the causes of birth defects. You helped us learn a lot about this topic, but there is still a lot to learn about what causes babies to be born with birth defects. To help us better understand how genes and other biologic factors play a role in birth defects, we would like for you to give us permission to use your **children's** leftover newborn bloodspots.

Since your baby was part of a **<twin/triplet/other>** birth, we would also like to request some of the leftover newborn bloodspots from your baby's **<twin/triplet/other> live born siblings**. Multiple births are especially informative for researchers who study genetics and birth defects.

When your children were born, the doctor, nurse, or midwife collected a few drops of blood from each of your **<twin's/ triplet's/ other's >** heel onto a card, we call these "newborn bloodspots." This is done on every baby in New York State to check for rare inherited conditions. These bloodspot cards are saved at a lab. We would like to use the leftover bloodspot samples from your children to study genes and other factors that might cause 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.

Your **children's** newborn bloodspot data and some limited other information (such as your **children'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 **children's** names will not be included in the databases. The other information included, such as your **children'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 children. A researcher who wants to study your **children'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 **children's** information. Researchers who are given access to the data will be agreeing to use appropriate security measures.

There is no physical risk because the bloodspots have already been collected from your children shortly after birth. To protect your **children'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 children. Because genetic information is unique to each person, there is a small chance that someone could trace it back to your children if they have another source of their 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 **children**. There is also a chance your **children's** information could be improperly released. The risk of this happening is very small and we have many safeguards in place to keep your **children's** information confidential. Additionally, there are state and federal laws that protect against genetic discrimination.

There is no personal benefit to your children 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 children in any way.

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. The Certificate of Confidentiality prevents study staff from being forced under a court order or other legal action to identify your children 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.

There is no cost for participation. 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.

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 **children's** newborn bloodspot samples, the sample data, and the interview data removed from the study at any time. In addition, when your children reach the age of 18, they can also contact the study and request to withdraw. After receiving this request, we will remove your **children'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.

The BD-STEPS studies that will be done on the leftover newborn bloodspots are not meant to test the medical status of your children. We will not return your **children'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 children, we recommend that you consult your health care provider.

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. The samples will remain under the ownership of the New York State Department of Health's Newborn Screening Program.

Your **children's** newborn bloodspot samples or newborn bloodspot data will not be used for commercial purposes.

Do you have any questions?

[If the parent has questions about the children's rights as research subjects, provide the contact information for the NYS IRB: For questions about your children's rights as subjects in this research study, please call Tony Watson of the New York State Department of Health Institutional Review Board at 1-518-474-8539. Leave a message including your name, phone number, and refer to Protocol #13-045, and someone will call you back as soon as possible.]

If not, I am going to read the consent to you. Please provide the name and birth order of each child for whom you would like to give permission to request some of their leftover newborn bloodspot. This consent is for:

Name of child for whom you answered the interview questions:

_____

Circle the order of delivery for this twin/triplet/other:

First Second Third Other (list)_____

Name of child's multiple (twin/triplet/other) sibling:

_____

Circle the order of delivery for this twin/triplet/other:

First Second Third Other (list)_____

Name of child's multiple (twin/triplet/other) sibling:

_____

Circle the order of delivery for this twin/triplet/other:

First Second Third Other (list)_____

Name of child's multiple (twin/triplet/other) sibling:

_____

Circle the order of delivery for this twin/triplet/other:

First Second Third Other (list)_____

I give permission for my children's leftover newborn bloodspots to be requested from the New York State Department of Health's Newborn Screening Program. These samples have already been collected and no additional 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:_____