Additional Study: Neonatal Blood Spot Acquisition

Purpose of the Additional Study
You have already agreed to participate in Upstate KIDS, a survey of children’s growth and development being conducted by the New York State Department of Health in collaboration with the State University of New York at Albany and the National Institute of Child Health and Human Development. Additionally, we would like to ask your permission to acquire your child’s newborn blood spot, which has already been collected shortly after your child’s birth by the New York State Newborn Screening Program.

Description
The New York State Newborn Screening Program routinely collects a few drops of blood onto a card from every baby born in New York to check for certain rare inherited conditions, such as congenital hypothyroidism, phenylketonuria, and sickle cell disease among many others. They usually have leftover blood spots, which are eventually discarded. The state lab has agreed to let us have a leftover blood spot from your baby if we have your permission. The blood spot samples will be used to look for any signs of undetected infections and whether New York State infants are being exposed to chemicals. The information derived from our analyses will be used for research purposes only and will not be useful on an individual basis because the kinds of laboratory analyses we are doing have no known value to doctors at this time. There is no further blood sample collection from your baby, as we will use leftover blood spots that have already been collected from your baby. We will use the bloodspots to measure various factors which might affect your child’s development. This will include environmental chemicals, heavy metals, and markers of your child’s immune status called cytokines, proteins in the blood that regulate the response of your immune system. We will not be measuring any medications or drugs. We will not be doing any genetic analysis on the blood samples.

Voluntary Participation
Your participation in this study is voluntary and you may stop at any time. You may also elect not to participate in this portion of the study and continue participating in Upstate KIDS Infant Development Screening Program. You and your child’s relationship with your doctors and the state agencies affiliated with this survey will not change as a result of whether you choose to participate in the survey or not. There will be no penalties to you or your child if you elect not to participate or if you choose to skip any portion of the study.

Potential Risks and Discomforts from Participation in this Study
There is no further blood draw from your child, so there are no expected physical risks. To protect your confidentiality, no names or other personal information will be attached to any samples. Only ID numbers will show on biologic samples.
Potential Benefits
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 biologic determinants of infant health and development. This information will be helpful to all individuals of childbearing age, or who may have children someday. We will share what we learn with other health professionals through medical publications. None of these publications will include information which could identify you or your child in any way.

Incentives
There are no additional incentives for giving us consent to obtain the leftover blood spot from your baby. However, you will continue to receive small gifts for each subsequent survey that you return as participation in the overall Upstate KIDS study.

Confidentiality
All of your personal information will be kept strictly confidential and will not be shared with anyone outside of the survey project unless you agree to do so or unless disclosure is made to protect you or another from serious harm. All of the information compiled for recruitment purposes and all completed survey materials will be kept locked in filing cabinets and on secure computer servers accessible only to the survey project team. Collaborators for this survey, including those from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, will only be able to access de-identified information you provide. Knowledge that is gained from this survey may be published in scientific journals without identifying names of the subjects. A Certificate of Confidentiality has been obtained under Section 301(d) of the Public Health Service Act (42 U.S.C. 241 (d)). This 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 participated in the research during any time the Certificate was in effect. Officials checking on the quality of the research may review records from this study. Such inspections are conducted in strict confidence according to Federal law.

Costs to you
There are no monetary costs for you to participate in this survey project.

Alternatives to participation
The alternative is to not participate in this survey. You do not have to participate if you do not wish to. Your rights as a participant are described in detail below.

In case of harm
Since this part of the project involves the analysis of a blood spot that has already been collected from your newborn baby, the risk to you and your child is considered minimal. We do not anticipate that you will suffer any physical harm as a result of participation. However, if this is a concern to you, you may choose to not participate.
If you have questions:

- If you have questions about the survey, you may contact the project’s Principal Investigator, Dr. Charlotte Druschel, Medical Director, Bureau of Environmental and Occupational Epidemiology, New York State Department of Health, 547 River Street, Flanigan Square, Room 200, Troy, NY 12180, telephone: 1-888-296-8192 or the Survey Coordinator, Ms. Elaine Hills, University at Albany, School of Public Health, One University Place, Room 216, Rensselaer, NY 12144, telephone: 1-888-870-0247.

- If you have questions about your rights as a survey volunteer, or if you are not satisfied with the manner in which this survey is being conducted and would like to discuss your participation in this study, please contact Mr. Tony Watson, Administrative Coordinator, Institutional Review Board, New York State Department of Health, Room 474, Corning Tower Building, Empire State Plaza, Albany, NY 12237, telephone: 1-518-474-8539

Your rights as a survey participant:

- Your participation in this survey is voluntary. You do not have to be in this survey if you do not want to be. If you decide not to participate, this will not affect any benefits to which you are otherwise entitled.

- After the survey is complete, all links to your personal identifying information will be destroyed.

- You should keep this consent form after detaching and returning the last page.

If you wish to ask any questions about the survey before signing, you may contact Dr. Charlotte Druschel or Ms. Elaine Hills at the addresses or phone numbers above.
Please complete the information below if you would like to participate:

Thank you for deciding to participate! Please complete the form below and return it to us in the envelope provided.

Your signature on this form means that you have:

- read the information given in this consent document, and
- you understand what might be expected from you by participating, and
- you understand that there will be multiple contacts over the next 36 months, and
- you would like to be a volunteer in this survey.

Participant (Mom’s) Name (Please Print)  Participant (Baby’s) Name (Please Print)

Participant Address

Participant Home Phone  Participant Cell Phone

Participant Signature  Date

Do NOT sign this form after Expiration Date
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