The Children's Hospital *of* Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title: **A Longitudinal MRI Study of Infants at Risk for Autism**

Version Date: November 16, 2016

Consent Name: Tooth Collection – Online Consent

Principal Investigator: Robert Schultz, PhD Telephone: 267-426-7540

Your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Why are you being asked to take part in this study?

You child is being invited to take part in this portion of the study because your family is participating or has participated in the Infant Brain Imaging Study.

What is the purpose of this research study?

The purpose of this portion of the study is to study how factors in the environment may affect the brain as babies develop in the womb. Because parts of teeth are formed right before birth and in the first 6 months of infancy, your child's teeth can tell us what environmental chemicals your child may have been exposed to before and after birth. Through this study we hope to learn how these chemicals impact health outcomes and also learn more about using this method to measure prenatal exposure to chemicals in the environment.

What is involved in the study?

How long will you be in this study?

Your child's participation will involve providing teeth as they fall out or are removed by a dentist. This involvement will end when your child stops shedding teeth.

What are the study procedures?

When your child's teeth fall out, or are removed by a dentist, we will ask you to put the teeth in small tubes we provide you, fill out a brief questionnaire for each tooth and mail the package to us in a prepaid mailer.

We will ask for up to 4 teeth during the research period. You may send fewer than 4 teeth. If some teeth you give us have cracks or cavities, we may ask for additional teeth. In these cases, we may actually collect more than 4 total teeth. We will send the teeth to a lab that specializes in this type of chemical analysis.

What are the risks of this study?

There are no known risks to collection of teeth that have fallen out or removed by a dentist.

Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. We hope that in the future, the knowledge gained from our study would benefit our understanding the association between environmental chemicals and health outcomes. You will not receive individual results about the chemicals measured in the teeth that you provide because we are still trying to learn if these exposures have any real influence on neurodevelopment. That means that these measurements do not yet have any meaning in terms of clinical decisions you might make for your child or your family.

Do you need to give your consent in order to participate?

If you decide to participate in this portion of the study, you must tell us that you agree. A copy will be sent to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this portion of the study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this particular research, health information about you will be collected. This will include information from questionnaires and collection of teeth. Information related to your medical care at CHOP will go in your medical record. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP and the University of North Carolina;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The National Institutes of Health (NIH), Autism Speaks, and the Simons Foundation, who are the study sponsors;
- Mount Sinai School of Medicine, who are analyzing the teeth;
- The Data Coordinating Center in Montreal who will receive study data without any identifying information.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By agreeing to participate you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Robert Schultz
The Children's Hospital of Philadelphia
Center for Autism Research
3535 Market St., Suite 860
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this portion of the study. The costs of mailing the teeth will be covered by the study.

Will you be paid for taking part in this study?

You will be compensated for your time participating in this part of the study. After the first mailer is received we will mail you a $25 gift card. Remember, we are hoping to get up to four teeth and you may not have four teeth to send in the first mailer. That's OK; we want any teeth you have to give as soon as possible. But if you do then send in additional mailers with more teeth, we will NOT be sending an additional gift cards after receipt of those other mailers.

The other thing that we will do for you is to include four $1 bills - each attached to the individual tooth information forms – so that you can have a dollar bill handy the next time any child in the family loses a tooth in case the "tooth fairy" visits your household.

Who is funding this research study?

The NIH is funding this part of the study as part of the Environmental Influence on Child Health Outcomes (ECHO) project. Autism Speaks, NIH, and the Simons Foundation are providing funding for the main study.

What if you have questions about the study?

If you have questions about the study, call the principal investigator, Dr. Schultz at 267-426-7540. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes

sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

Please contact the study coordinator at 267-426-7540 if you have questions about the study or this form. Did you email or call anyone for help or clarification about this form?

If you received help or clarification about this form, please write in the name of the person who assisted you.

Name _____ Date You Were Helped _____

By checking the box below, you are saying that you have had your questions answered and you agree to take part in this research study and that you are legally authorized to consent to participation. You are also agreeing to let CHOP use and share your health information as explained above. If you don't agree to our collecting, using and sharing your health information, you cannot participate in this study. **Note: A foster parent is not legally authorized to consent for a foster child's participation.**

Name of Subject –AUTO COMPLETED _____

Name of Person Completing Enrollment - - AUTO COMPLETED _____ Date – AUTO COMPLETED _____

◯ CHECK HERE TO CONSENT TO PARTICIPATION IN THIS RESEARCH STUDY