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Written / On-Line Consent Form

Study Title: **IBIS: Environmental Factors That May Influence the Occurrence of Autism**

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Version: On-line Consent

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Because your child has taken part in the Infant Brain Imaging Study (IBIS), you and your child are invited to join a related research study exploring how environmental exposures affect brain development.

This consent form describes the study's purpose, procedures, benefits, and risks. If there is anything in this form you do not understand, please ask questions. Declining to be in the study, or leaving the study early, will not affect your relationship with the researchers, health care providers, or the University of Washington.

In the sections that follow, the word "we" means the study investigator and other research staff. "You" refers to the biological mother and child enrolled in IBIS. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." Please take time to make your decision and discuss it with family and friends.

What is the purpose of the study?

You previously agreed to allow your child to participate as a research subject in a study called "Brain Development in Infants at High Risk for Autism." As part of that project, this related study explores how air pollution, metals, chemicals, and other factors influence children's brain development and behavior.

This study will examine environmental risk factors as they relate to the occurrence of ASD and alterations in early brain and behavioral development. This will be done in two ways: 1) we will collect shed deciduous teeth (baby teeth) for examination of metals and organic compounds and 2) we will collect information on past and current residential locations for assignment of air pollution exposure. We will be able to use this information in conjunction with other information collected as part of our IBIS project.

The information we collect about your residential locations will be linked to a national database located at the University of Washington that provides information on local air quality and pollution levels at these locations. By collecting your child's shed deciduous teeth (baby teeth), we will be able to quantify prenatal deposition of selected heavy metals (lead) and organic pollutants (organochlorine pesticides, PCBs, and phthalates) in dental tissues as an exposure biomarker.

We hope to link air quality measures, pre and postpartum, and environmental toxins exposure levels to brain and behavior measures already collected as part of IBIS. We will also use genetic material (DNA) that your child has already provided to explore the role of genetic susceptibility in modifying the effects of environmental toxin exposure on the expression of ASD-related phenotypes.

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How many people will take part?

A total of approximately 700 mother/child pairs at the 4 IBIS institutions will take part in this study, including approximately 150 families from the University of Washington.

What is involved in the study?

If you and your child take part in this research study, you would be asked to do the following:

- a. **Shed Teeth:** We would ask to collect samples of shed deciduous teeth (baby teeth) from your child to allow us to do some basic testing of possible exposure to environmental toxins. We would collect up to 5 shed teeth using a tooth collection container. Collecting these teeth samples would only take a couple of minutes. We would mail you a "Tooth Fairy Kit" containing tooth collection tubes, a tooth donation form, a Tooth Fairy receipt and a \$1 bill, and a postage-paid padded envelope. We invite you to donate up to 5 baby teeth lost by your child who is enrolled in IBIS. We will send you a \$20 check when we receive the donated teeth. Any teeth that we do not immediately use may be stored for future analysis. Sorry, but we cannot return any teeth. **It is very important that you donate teeth ONLY from your child who was enrolled or is currently enrolled in IBIS.**

Children lose their baby teeth at different ages. Teeth you have already saved from your child can be used. We will ask you to put each donated tooth in a separate tube and close the lid securely. You don't have to fill all 5 tooth tubes; we welcome any number you would like to send, up to 5. For each tooth, note on the IBIS Tooth Donation form the date (or best estimate) when it was lost, how it came out, and how it has been stored. Place the tubes inside the lavender bag and the collection form in the pre-paid padded envelope to be mailed to us. The \$1 bill and commemorative tooth receipt are yours to use the next time your child loses a tooth or as you see fit!

If you want to participate and don't currently have baby teeth available, save the kit for the next time your child loses a tooth. If you send fewer than 5 teeth, we may contact you in the future to ask if you want to send more teeth. Please call the study team at (206) 543-2125 if you have questions or need additional tooth collection materials. We anticipate collecting baby teeth through July 2020.

- b. **Residential History Form:** We would ask you to provide us full addresses and dates of residence of any homes or apartments spanning the time between three months prior to conception through the 36-month period of follow-up for your child enrolled in IBIS. Your contact information will be housed locally at the University of Washington. You can fill out a written form or we will have a web-based form for you to answer on-line. A research coordinator will send you a unique link for completion of the on-line Residential History form. Entered data will be sent via secure encoded transfer back to the IBIS data repository and stored at UW to preserve confidentiality. Each address provided will be converted from a postal address to a numerical code that specifies its spatial location on a map (referred to as a "geo-code"). Completed geo-codes will be sent via secure encoded transfer for exposure assignment at the University of Minnesota.

How long will you be in this study?

If you decide to take part, you can opt to do both the address collection and the baby teeth collection, or just one of the two parts. Your participation in the address collection would last less than 30 minutes. Your participation in the baby teeth portion could be as short as 30 minutes (to gather your child's lost baby teeth, fill out a form, and send back a pre-paid mailer) or as long as

12 months if you are waiting for your child to lose teeth. Any teeth not used in the immediate analysis will be stored for potential future use.

What are the study procedures?

Written/On-line Consent: You will be asked to complete this consent form, indicating whether you agree to the baby teeth donation or the air pollution address project, or both of these projects. If you consent, you will be asked to complete an IBIS Written/On-Line Residential History form.

Written/On-line IBIS Residential History form: If you consent, you will be asked to provide an address history for the air pollution portion, you will fill out a written form or you may follow an email link and enter prior addresses on-line.

Tooth Fairy Kit: If you consent to donating up to 5 of your child's baby teeth, you will be mailed a Tooth Fairy Kit containing 5 small tubes (ToothTubes). We will also ask you to complete an IBIS Tooth Donation form that will be provided in the kit. The kit also has a Tooth Fairy receipt and \$1 bill to go under your child's pillow next time he or she loses a tooth. You can donate previously lost teeth or wait for the next lost tooth. *We cannot return donated teeth.* In addition, a lavender bag will be provided to store the shed tooth inside the ToothTube.

ToothTube: Place the shed tooth into the ToothTube. We will ask you to place one shed tooth for each ToothTube. You may donate up to 5 shed teeth; 5 ToothTubes will be provided in the kit.

Lavender Bag: Place the ToothTubes inside the lavender bag and the IBIS Tooth Donation form in the pre-paid padded envelope to be mailed to us.

What are the risks of the study?

There are no foreseeable risks or discomforts. There always exists the potential for loss of private information; however, procedures are in place to minimize this risk.

Are there benefits to taking part in this study?

Research is designed to benefit society by gaining new knowledge, such as finding risk factors for autism spectrum disorder (ASD). You will not receive any direct benefit from this study. You will not receive individual results about your child's environmental exposures because the information obtained is for research purposes and is not intended to suggest treatments or clinical information to your family.

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

If you decide to participate in either or both parts of this study, you must review and acknowledge reading this form. We can provide a written copy or you may print a copy as a record.

What happens if you decide not to take part in either or both parts of the study?

Participation is voluntary. You do not have to take part either or both studies to receive care at the University of Washington. 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 and confidentiality?

All research projects carry some risk that information about you may become known to people outside of a study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the University of Washington

will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University of Washington, research sponsors, or government agencies for purposes such as quality control or safety.

We take precautions to protect your personal information and will use it only for the purpose of this study. In any publication or presentation of research results, you will not be able to be identified.

How will be information be protected?

For the address history, we will assign you a study ID to keep your name private. After you provide your address history, the information will be stored on a secure server and encrypted. Only your IBIS site and an IBIS-approved researcher who will geocode the addresses will know your information.

For the baby teeth, your child's samples will be identified by a code, not a name. The tooth samples will be securely stored at a laboratory collaborating with and authorized by the study. Identifying information will be removed from the samples and replaced with the code. Only research staff will be able to connect that code number with identifying information.

Other Information You Should Know

You will not own the baby teeth after you give them to the study, and they cannot be returned. Your child's tooth specimens will be stored and might be used for future research. They will be used for research purposes only and will not be sold. There is no set time for destroying the information and tooth specimens that will be collected. Your permission to use and share the information and data from this study will continue after 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?

Taking part in research is always a choice. If you change your mind and choose to leave the study, it will not affect your care at the University of Washington. To take back your permission, you must tell the investigator in writing.

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University of Washington, Department of Radiology - Box 357920
Seattle, WA 98195

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

Financial Information

Will there be any additional costs?

There are no costs to you or your insurance for taking part in the study.

Will you be paid for taking part in this study?

You will not receive compensation for providing address information. You will receive a \$20 check and \$1 for your time and effort for providing baby teeth. Please allow up to six weeks for the check to be processed.

Who is funding this research study?

The National Institutes of Health and the Wendy Klag Center for Autism & Developmental Disabilities at the Johns Hopkins Bloomberg School of Public Health.

What if you have questions about the study?

If you have questions later about the research, or if you have been harmed by participating in this study, you can contact one of the researchers listed on the first page of this consent form. If you have questions about your rights as a research subject, you can call the UW Human Subjects Division at (206) 543-0098.

Consent to Take Part in the Study

Please contact the study coordinator at (206) 543-2125 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.

Study Coordinator's Name

Date You Were Helped

By checking the boxes below, you are saying that you had no questions or have had your questions answered; that 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 the University of Washington and other IBIS investigators use and share your information as explained above. If you don't agree to our collecting, using and sharing your information, you cannot participate in this study.

Parent's Agreement for baby teeth collection

I have read the information and have no questions. I voluntarily give permission to allow my child to participate in this research study through the donation of 1 to 5 of his or her baby teeth.

Printed Name of Child

Printed Name of Person Completing

Date

Signature of Person Completing

Date



IF ONLINE, CHECK
HERE TO CONSENT TO
PARTICIPATION IN THIS
RESEARCH STUDY

Biological Mother's Agreement for air pollution address collection

I have read the information and have no questions. I voluntarily give permission to provide my home address history related to pregnancy, and my child's address history from birth to age 3.

Printed Name of Biological Mother

Printed Name of Child Subject

Printed Name of Person Completing

Date

Signature of Person Completing

Date



IF ONLINE, CHECK
HERE TO CONSENT TO
PARTICIPATION IN THIS
RESEARCH STUDY