



LETTER OF INFORMATION & CONSENT

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| Title | Ontario Birth Study Kids (OBS-Kids) |
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INTRODUCTION

Thank you for your participation in the Ontario Birth Study and your agreement to be contacted about future studies to follow-up with you and your child (if you have more than one OBS child, please consider all the procedures below to refer to all children). We are now asking you to participate in our follow-up study described below.

Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about OBS-Kids with anyone you wish. Participation is voluntary.

BACKGROUND AND PURPOSE

The Ontario Birth Study was created to help us study how things that happen in pregnancy can affect the health and development of the child at birth and while they grow up. We are now following up with children to study their health and development. Our long-term goal is to learn more about what affects child development and what we can do during pregnancy and early life to help children remain healthy and develop to the best of their potential.

Any information gathered from questionnaires and other measurements as well as biological samples collected for the study will be stored and only authorized research personnel can gain access for studies that have passed ethical review. The samples will be processed and stored at the Biospecimen Repository at the Lunenfeld Tanenbaum Research Institute of Sinai Health System.

ONTARIO BIRTH STUDY KIDS (OBS-Kids) DESIGN

We will collect information from you and your child via phone interviews. If permitted by Public Health Authorities under current situations, we will also collect information during visits at your home at some time points. A visit can be done in the hospital if the study visit cannot be done at your home. The method of data collection will depend on the age of your child. We will use the following schedule:

8 months: phone interview
24 months: phone interview and/or home visit
36 months: phone interview
4.5 years: phone interview and/or home visit

STUDY VISITS AND PHONE INTERVIEWS

The procedures at each follow up are described below. If your child is older than some of the time points we will begin with the next upcoming age visit or interview. We will contact you a few weeks in advance to schedule a phone interview and/or home visit at each follow up. You can choose to skip any time point or skip any part during the phone interview or home visit that you do not wish to complete.

8 month phone interview: We will ask some questions about if and how long you breastfed, about your child's health and sleep patterns, about you and your child's father, about any smoking in the household, and about your childcare arrangements. At the end of the phone interview, we will also invite you to complete an online questionnaire that includes questions about how your child regulates their thinking and behaviour. **The phone interview will take about 15 minutes and the online questionnaire will take an additional 10-15 minutes to complete**

24 month phone interview and/or home visit: During the phone interview, we will update your child's health and ask questions about your child's development (whether your child does different activities such as identifying pictures and running that are common in children about this age) as well as updating some information from you and recording information from your child's vaccination booklet. If permitted by Public Health Authorities and if you agree, we will arrange a home visit. During the home visit, we will measure your child's height and weight, and will ask you and your child to do a simple task together that we will film it for 5 minutes. Also, if you consent, we will collect a saliva sample from your child. The saliva sample can be used for genetic studies and to see if your child has been exposed to some types of viruses. **Alternatively, if you do not prefer an in-person study visit or if your home is not within the travelling radius of our team, a virtual meeting for the mother-child task activity can be arranged. The virtual meeting will be recorded. The phone interview will take 30-40 minutes of your time and the home visit /virtual meeting will take an additional 20-40 minutes of your time.**

36 month phone interview: We will update information about your child and ask some additional questions about your child's time with screen devices such as TV's or tablets and about international travel. At the end of the phone interview, we will also invite you to complete an online questionnaire that includes questions about how your child regulates their thinking and behaviour. **The phone interview will take about 15 minutes. If this is the first or second follow up with your child, a longer questionnaire will be used and the interview will take about 30 minutes. The online questionnaire will take an additional 10-15 minutes to complete.**

4.5 years phone interview and/or home visit: During the phone interview, we will update your child's health, ask you some questions about your child's mood and behaviour, update information about your family, and update your child's vaccination information. If permitted by Public Health Authorities and

if you agree, we will arrange a home visit. During the home visit, we will measure your child’s height and weight, and ask your child to complete some tests using an iPad. These tests are like games and are about matching shapes and colours or are word games that tell us about your child’s thinking and memory. These tests have been used in children aged 3 to 7. If you agree, we will also collect a saliva sample from your child. **The phone interview will take 30-40 minutes of your time and the home visit will take an additional 50 minutes of your time.**

Saliva sample collection: At 24 months we will use a small sponge on a stick to collect saliva from your child’s cheek and gums. At 4.5 years we will ask your child to rinse their mouth with water, put ¼ teaspoon of sugar on their tongue, and ask them to spit into a container. This only takes a few minutes.

Below is a table that shows what happens at each follow up.

| Child’s age | Phone Interview | Study visit | Collecting child’s saliva sample | Time |
|-------------|-----------------|---|----------------------------------|--------------------------------------|
| 8 months | X | | | 15 minutes + 10-15 minutes online |
| 24 months | X | X (Purpose: Measure child’s height and weight, ask mother and child to do interaction activity and film) | X | 30-40 minutes + 20-40 minutes |
| 36 months | X | | | 15-30 minutes + 10-15 minutes online |
| 4.5 years | X | X (Purpose: Measure child’s height and weight, ask child to do tests on iPad) | X | 30-40 minutes + 50 minutes |

POTENTIAL DISCOMFORT AND RISK

There are no risks to you or your child by participating in OBS-Kids.

Your child may become tired or distressed during the home visit. If this happens you can skip parts of the visit or stop the visit if you wish. The research assistant may also stop the visit. This will not affect your overall participation in the study.

It is possible that we may identify a developmental problem or possible problem in your child that you do not already know about. Experts on our study team will review these situations and we will let you know if there is anything they feel you should discuss with your child’s primary care provider.

As part of this study we will ask you to complete study interviews that include some sensitive topics. You may feel uncomfortable in answering these questions and you have the option to skip over or stop answering the questions at any time. This will not affect your overall participation in the study. OBS-Kids team members and your primary care provider will be available to you to discuss any feelings that you may be experiencing and help you to get assistance in dealing with these emotions.

BENEFITS TO PARTICIPATION

Although there are no direct benefits to you personally for participating in this study, your participation may help provide new knowledge about child development. It may also assist in developing useful recommendations for pregnant women and young children to help children reach their potential. It will also help inform other studies regarding pregnancy and its long term impact on the health and well-being of mothers and children.

VOLUNTARY PARTICIPATION

Your participation in this study is completely voluntary and you can choose to stop at any time. Choosing not to participate or deciding to withdraw from the study will not affect your or your child's health care and will not prevent you from participating in other studies.

Should you choose to withdraw from OBS-Kids, you will have the following withdrawal options:

- (a) No further Contact: This means that we will not contact you any further about OBS-Kids or any related studies. We will continue to use any information that we have already collected from you through the Ontario Birth Study or any follow-up information you have provided.
- (b) No further Use: This means that we will not contact you any further about OBS-Kids or any related studies and any information or samples you have already provided will be removed from our databases and repository. It will not be possible to remove samples and/or information that have already been given to researchers for analyses.

CONFIDENTIALITY

Personal Health Information

For OBS-Kids we will collect personal health information directly from you and your child that will extend and update what we have already collected in the Ontario Birth Study. Representatives of the Sinai Health Research Ethics Board may look at the study records and your personal health information to make sure the study follows proper laws and guidelines. Strict privacy practices will be followed to protect your confidentiality and your information will be stored securely. No identifying information, including any video recording, will be sent outside Sinai Health System when we collect information, unless the law requires us to do this. For example, the law requires us to give information if a child has been abused.

Personal health information is anything that can be used to identify you and can include your:

- Name
- Email address
- Postal address
- Phone number
- Date of Birth

Some study communications will be handled by email which is not a secure means of communication. However, every effort is made to maintain confidentiality and avoid discussing personal information by email.

The information that is collected for the study will be kept in a locked and secure area for about 50 years unless you choose to have it removed. Only the study team or researchers doing approved studies will be allowed to look at your records.

The video recording at the 24 month visit will be destroyed after 6 months.

Study Information that Does Not Identify You

The research information will be shared with other researchers, but any information about you that is sent outside of the hospital will not identify you.

All information collected during these studies, including your personal health information, will be kept confidential and only be shared with partner organizations. You will not be named in any reports, publications, or presentations that may come from these studies.

Some of your information may be stored outside of Canada but without any information that identifies you. It will be subject to privacy laws that may differ from Canadian laws. Personal identifying information will be encrypted and stored only on secured servers within Sinai Health System. We will take all reasonable steps to protect your privacy.

IN CASE YOU ARE HARMED IN THIS STUDY

If or your child become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered by any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

EXPENSES ASSOCIATED WITH PARTICIPATING IN THIS STUDY

Participation in this study will not involve any additional costs to you.

GIFT

We will give you a small thank-you gift such as a toy for your child and a notebook for yourself as a thank you at each home visit.

DEVELOPMENT FOR COMMERCIAL GAIN

Research carried out on information and samples collected may lead to the development of marketable treatments, devices, new drugs or patentable procedures. By giving your information and samples to OBS-Kids, you will not benefit directly from any such commercial products. Any such benefits will remain with the study research partners. You will not receive any financial benefits for participating in this study.

FUTURE RESEARCH ON THE DATA AND BIOLOGICAL SAMPLE BANK

To access the information and/or samples in the 'bank', any future research will be approved by the Ontario Birth Study Steering Committee as well as all relevant Research Ethics Boards.

If your child provides a saliva sample, it will be possible for researchers to look at their DNA for genetic studies. The DNA will be stored until the child is 18 when they will be asked for consent to store it for a longer time.

Researchers who use your information and samples in the future might discover something unexpected (known as an 'incidental research finding') that could significantly affect your child's health. The decision to communicate any incidental research findings to you will be determined on a case-by-case basis in accordance with the Research Ethics Board.

QUESTIONS ABOUT OBS-Kids

If you have any questions, concerns or would like to speak to the study team for any reason, please call 416-586-4800 ext.8119 or email OBSkids@lunenfeld.ca. For more information please visit the Ontario Birth Study website at <https://ontariobirthstudy.com/participants/obs-kids-follow-up/>

If you have any questions about your rights as a research participant or have any concerns about this study, please contact the Research Ethics Office at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

REMINDERS

It is important that you do the following things during this study if applicable:

- Ask your study team about anything that worries you.
- Tell study team if you change your mind about being in their study.

YOUR CONSENT

By submitting this *Consent Form*, I am agreeing to participate in OBS-Kids and declare that:

- I have read and understood the information provided to me. I have had the opportunity to ask questions and received satisfactory answers. I was given enough time to think it over and decide about my participation.
- I understand that I will be asked to: (i) answer questions about myself and my child, (ii) have my child's height and weight measured, and (iii) have my child answer questions about colours, shapes, and words. I understand that I can choose not to answer any question or not have my child do a part of the study if it makes me uncomfortable.
- I understand that I may be asked to be filmed with my child for a few minutes while we do a task together and I can choose not to do this.
- I accept that the information that my child and I provide, after our names and other identifying information have been removed, may be used by researchers from Canada and other countries for approved health-related research projects.
- I understand that my participation is completely voluntary and that I can withdraw from OBS-Kids at any time, without giving a reason, by contacting the *Ontario Birth Study or OBS-Kids*. If I do withdraw, I understand that I will have various options about what happens to the information I have already provided. I further understand that any information I provide will continue to be available to researchers if I can no longer make decisions for myself, or after my death.
- I accept that I will receive no personal financial benefit from the sale of any test or product that may be developed as a result of the data and samples collected by OBS-Kids.

- I accept that the information other than recorded video collected by OBS-Kids will be kept for about 50 years. At this time, ethics experts will decide if information should be destroyed, made anonymous, or kept for further research.

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

Print Study Participant's Name _____
Print Child's Name _____
Relationship to Child

Signature _____
Date
(You will be given a signed copy of this consent form) My signature means that I have explained the study to the participant named above. I have answered all questions.

Name of Person Obtaining Consent:

Print Name _____
Signature _____
Date

Consent for saliva

- I agree to have my child give a saliva sample for research purposes including research in genetics. I understand that I will not be given results from the saliva sample, except in unusual situations with potential clinical relevance after expert and ethics review.

I agree I disagree _____ Participant initial

- Government funding agencies and some research journals have data sharing policies that require research information from biological samples to be shared anonymously with the research community. I agree that information from my child's saliva sample can be shared anonymously when required.

I agree I disagree _____ Participant initial

Consent for email

- I consent to providing my email address for the purpose of study communication and follow-up. This may include follow-up for future studies if I have agreed to be contacted. I understand that email is not a secure form of communication.

I agree I disagree _____ Participant initial

Consent for medical record

We are asking your permission to access information collected by other organizations about your child's health. For example, the Ontario Health Insurance Plan (OHIP) Claims Database contains information about claims paid for by OHIP, such as services provided by physicians and laboratories. Another example is the Better Outcomes Registry & Network Ontario (BORN), which keeps a highly confidential maternal-child registry. We are also asking your permission to link to relevant databases that may be developed in the future. Linking to this information gives researchers a more complete picture of specific health care issues than can be achieved with unlinked information.

- I give my permission for the *Ontario Birth Study* to access information in administrative or medical databases (e.g., the Better Outcomes Registry & Network Ontario) and to record my child's OHIP number for this purpose. I understand that at all times my child's personal information will be protected and my confidentiality maintained.

I agree

I disagree

_____ Participant initial