

LETTER OF INFORMATION & CONSENT

Title	Ontario Birth Study
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**Members of the Steering Committee*

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INTRODUCTION

You are being asked to take part in a research study about your current pregnancy (“The Ontario Birth Study”). In addition to asking questions about your current pregnancy, the Ontario Birth Study plans to continue to follow-up your child’s health once they are born.

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 doctor or 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 the Ontario Birth Study with anyone you wish. Participation is voluntary.

BACKGROUND AND PURPOSE

There is a recognized need for long-term evaluation of women’s and infants’ health. This includes better understanding of early life factors that determine health and disease. The overall aim of the Ontario Birth Study is to develop a platform for future research on pregnancy complications and maternal and infant health, and ultimately, to assemble a cohort of studies in the future that investigate the developmental origins of health and disease.

Any information gathered from self-administered online questionnaires, hospital medical charts and biological samples collected for the purposes of the study will be stored in a confidential ‘bank’ of information to which only authorized research personnel can gain access for studies that have passed ethical review.

ONTARIO BIRTH STUDY DESIGN

This study is a form of observational research study. It does not involve any drug or treatment interventions. The Ontario Birth Study will collect questionnaire data and biologic specimens at different times throughout and after pregnancy.

STUDY VISITS AND PROCEDURES

As a participant in the Ontario Birth Study, we would ask you to:

1. Provide us with permission to access your patient chart for medical information about your pregnancy and delivery.
2. Provide an extra 20-40 cc of blood (about 2-3 tablespoons) at the time of your routine care. Please note, if you are not having clinical blood work done at one or more of the anticipated study time points, we will request that you provide a sample for the purpose of the study. During the COVID-19 pandemic you will not be asked to provide optional blood samples.
3. If you are admitted to MSH Labour and Delivery with a pregnancy complication prior to delivery (i.e. hypertensive disorder of pregnancy, fetal growth restriction, or threatened preterm labour), you may be approached by study staff to collect an additional 30-40cc of blood (2-3 tablespoons).
4. Complete questionnaires about your general lifestyle and diet.

CALENDAR OF VISITS

The following table illustrates what you can expect to happen at different time points throughout your participation in the Ontario Birth Study. The expected routine care visits are listed by gestational age.

Time of your routine visit	Blood work	Lifestyle Questionnaire	Diet Questionnaire	Approximate Time Commitment
Week 11 - 14	20-40 cc	Online	-	45 min
Week 16-20	20-40 cc	-	Online	45 min
Week 28	20-40 cc	Online	-	30 min
Delivery*	20cc	-	-	10 min
	Infant blood spot card			
6 weeks <i>after</i> Delivery	-	Online	-	30 min

*Women admitted to triage for a pregnancy complication prior to delivery admission may be requested to provide an additional 30-40cc blood sample if study staff available

The study questionnaires are self-administered and can be completed using a paper version or online.

Your blood samples will be processed and stored in the Biospecimen Repository at the Lunenfeld Tanenbaum Research Institute of Mount Sinai Hospital.

Twenty-four hours after birth, a blood spot card is routinely collected from your baby using a heel prick. The Ontario Birth Study will ask to collect one extra blood spot card at the time of heel pricking.

You may be approached at time of delivery by an authorized hospital research staff member asking if they can collect samples of your placenta or cord tissue. You can choose not to provide these samples if you feel uncomfortable, without affecting your participation in the Ontario Birth Study.

Please note: All study visits are scheduled to occur at the time you will already be at your obstetrician's office for routine appointments so the study will not require additional clinic visits.

PARTNER STUDIES:

OBS-Kids Follow-up:

We also encourage you to take part in a follow-up research study called OBS-Kids which picks up where the Ontario Birth Study leaves off by following your child's health as they grow and develop.

The OBS-Kids Follow-up study is based in the Lunenfeld-Tanenbaum Research Institute of Mount Sinai Hospital. We are inviting mothers who participate in OBS to also participate in OBS-Kids to help us to study what influences child development, particularly factors during pregnancy and in the neonatal period. Our long term goal is to find ways for children to reach their maximum potential. We would like to collect information from you and your child when your child turns 8 months, 24 months, 36 months and 4.5 years old, in the format of telephone interviews or home visits depending on the child's age. You can choose to participate or not to participate at each time point. We will ask you later in your pregnancy if you would like to participate in this follow-up study.

For more information please visit the OBS Kids website at <http://ontariobirthstudy.com/participants/obs-kids-follow-up/>.

Research Centre for Women's and Infant's Health BioBank (RCWIH):

The RCWIH is a program based at the Lunenfeld-Tanenbaum Research Institute of Mount Sinai Hospital which collects placental tissue and umbilical cord tissue and blood for research purposes to identify potential causes of pregnancy complications. If you experience complications during your pregnancy or you are eligible for specific research studies, you may be approached by the RCWIH Biobank staff to ask for your consent to collection of some or all of these specimens. You may also be approached if you are not having complications in order to collect normal specimens for comparison purposes.

LINKAGE TO HEALTH DATA

You will be asked if we can link the information that you provide in our questionnaires with your other administrative/medical data using your Ontario Health Insurance Plan (OHIP) number so that we can learn about how pregnancy and birth affects later health.

'Data linkage' means linking information about the same person from multiple sources. For example, every time you undergo certain tests conducted by a health care professional (e.g. a mammogram), these results are stored in a separate database. This is referred to as 'administrative data'. You will be asked if we can link the information that you provide in our questionnaires with your other administrative/medical data

POTENTIAL DISCOMFORT AND RISK

There are no risks to you or your baby by participating in the Ontario Birth Study.

However, since there will be withdrawal of blood you may experience slight bleeding, pain or discomfort at the site of needle insertion during blood draw. Very few people may develop a bruise, malaise, dizziness or infection. The infant blood spot card collection will be done following the standard procedure.

As part of this study we will ask you to complete study questionnaires 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 questionnaire at any time. This will not affect your overall participation in the study. Ontario Birth Study team members and your primary care provider will be available to discuss any feelings that you may be experiencing and help by getting you 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 and invaluable insight into a wide range of pregnancy-related conditions. It may also assist in developing useful recommendations for pregnant women and improved delivery of healthcare. It will also help inform other studies regarding pregnancy and its impact on women's long-term health as well as that of children.

VOLUNTARY PARTICIPATION

Your participation in this study is completely voluntary and you can choose to stop at any time. Refusal to participate or deciding to withdraw from the study will not affect the quality of care that you would normally receive during pregnancy and/or after delivery. Refusal to participate in the Ontario Birth Study will not prevent you from participating in future studies.

Should you choose to withdraw from the Ontario Birth Study, you will have the following withdrawal options:

- (a) No further Contact: This will not allow us to contact you in the future, nor ask you to join any on-going study activities. This allows us to keep your information already collected and continue to access information in administrative or medical databases.
- (b) No further Access: This will not allow us to contact you in the future, nor ask you to join any on-going study activities. Although we will continue to use information and samples that have already been provided by you, we would not be able to collect any further information about you from your administrative and medical databases.
- (c) No further Use: This will not allow us to contact you or ask you to participate in ongoing study activities. We would not be able to collect any further information about you from your administrative and medical databases. Any information or samples you have already provided will be removed from our databases. It will not be possible to remove samples and/or information already given to researchers for analyses.

CONFIDENTIALITY

Personal Health Information

If you agree to join the Ontario Birth Study, the study doctor and his/her study team will look at your personal health information and collect only the information relevant for the study. We will need to share your name, expected date of confinement (EDC) and Ontario Birth Study Identification number with our research team including the Lunenfeld-Tanenbaum Research Institute Biospecimen Repository and the RCWIH BioBank On Call staff to ensure the collection of specimens on admission to the labour floor as well as collection of the placenta following by the RCWIH biobank staff if you consent to this. Representatives of the Mount Sinai Hospital 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.

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

- Name
- Email address
- Postal address
- OHIP number
- Hospital medical record number (MRN)
- Date of Birth
- New or existing medical records that includes types, dates and results of medical tests or procedures.
- Estimated date of Confinement or due date

Some study communication will be handled by email which is not a secure means of communication; however, every effort is made to maintain confidentiality.

The information that is collected for the study will be kept in a locked and secure area for up to 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. Your participation in this study also may be recorded in your medical record at this hospital.

Study Information that Does Not Identify You

Our intention is to share study information with other investigators, however 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. It will be encrypted and stored on secure servers, but will be subject to privacy laws that may differ from Canadian laws. We will take all reasonable steps to protect your privacy.

IN CASE YOU ARE HARMED IN THIS STUDY

If you become ill, injured or harmed as a result of taking part, you will receive care. The reasonable costs of such care will be covered for 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

Since participation in this study will not involve any additional costs to you or your health-care insurer, you will not be receiving any out-of-pocket expenses for joining the study.

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 the Ontario Birth Study, 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 Committees.

Most of your blood samples will be frozen so that researchers can look at them in the future. Some of your blood samples may be stored for up to 50 years. Some of the studies that may be done with your sample will involve looking at blood markers, called biomarkers, of disease. By providing a blood sample, it will also be possible for researchers to look at your DNA and other parts of your blood.

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 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 THE ONTARIO BIRTH STUDY

If you have any questions, concerns or would like to speak to the study team for any reason, please contact: Ontario Birth Study at 416-586-4800 ext 6036 or OntarioBirthStudy.msh@sinaihealth.ca. For more information please visit the Ontario Birth Study website www.OntarioBirthStudy.com

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 the *Ontario Birth Study (OBS)* and declare that:

- I am 18 years of age or older. 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 detailed questionnaires about myself, my health, the way I live (e.g., lifestyle, diet), and where I spend my time (e.g., environment); (ii) report my height, weight; and (iii) provide biological samples such as blood. I understand that I can choose not to answer any question or report certain physical measurements if they make me uncomfortable.
- As part of routine clinical care, infant blood is collected at birth at which time heel pricks are routinely performed to collect infant blood on a blood spot card. I understand my participation in the Ontario Birth Study will allow one extra blood spot card to be collected for research purposes (infant DNA).
- I accept that my questionnaire answers, after my name and other identifying information have been removed, may be used by researchers from Ontario, Canada (for example, as part of larger studies being carried out across Canada), and other countries for approved health-related research projects.
- I understand that my participation is completely voluntary and that I can *withdraw* from the *OBS* at any time, without giving a reason, by contacting the *OBS*. 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 the *Ontario Birth Study*.
- I accept that the information collected by the *Ontario Birth Study* will be kept for at least 50 years. At this time, ethics experts will decide if information should be destroyed, made anonymous, or kept for further research.

I agree

I disagree

We are asking your permission to access information collected by other organizations about your 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 OHIP number for this purpose. I understand that at all times my personal information will be protected and my confidentiality maintained.

I agree

I disagree

- I give my permission for the *Ontario Birth Study* to contact me in the future to provide me with updates about the *Study* or other relevant health-related information and to ask me to give more information or measurements (e.g., additional questionnaires). I further understand that I may be contacted by *OBS* staff about other studies associated with the *Ontario Birth Study*. I recognize that I can refuse to participate at that time.

I agree

I do not agree

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

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