



RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

The Canadian Healthy Infant Longitudinal Development (CHILD) Study

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Major Funding Partners

Canadian Institutes of Health Research
Allergen NCE (the Allergy, Genes and Environment
Network of Centres of Excellence)

You are being invited to participate in a national research study directed by Dr. Malcolm Sears at McMaster University in Hamilton, Ontario, that will involve a total of 5,000 families from four regions across Canada; Toronto, Winnipeg, Edmonton and Vancouver. You are being invited to participate because you are planning to give birth at Mount Sinai Hospital or Sunnybrook Health Sciences Centre in the next year. We are planning to enroll approximately 1,500 families from Toronto.

The title of the study is “The Canadian Healthy Infant Longitudinal Development Study”. The term “longitudinal development” in the title of the study, means we want to observe your child’s growth and development over a period of years. This is a birth cohort study, which means all the children in this study will be born in the same period of time and will be studied at regular intervals over a 6 year period.

To decide if you want to be a part of this research study, you need to know what is involved and the potential risks and benefits of participating. This document gives you detailed information about the research study before you make a decision. If you decide to participate, you will be asked to sign the consent form at the end of this document. Please take your time to make your decision, and feel free to discuss it with your friends and family, or your family doctor.

Why is this Research Needed?

Over the past 30 years, there has been increasing concern about possible effects of the environment on children’s health. We usually think about the outdoor environment; however, since infants spend the majority of their time indoors, the effect of the indoor environment on health is also important. Our environment includes not only the air we breathe but also the food we eat, the infections we encounter and the stresses of life.

Purpose of the Research:

The main purpose of the CHILD Study is to find out how our Canadian environment and inherited genetic factors are related to health and development. One example of possible environmental health effects is the dramatic increase in allergic diseases, such as food allergy, eczema and asthma. We want to collect information about your child’s health and surroundings over the next five years to identify possible causes for these changes. This will help to make a healthy and safer environment in the future and improve the quality of life for all children. We are examining:

- **Genetic Factors:** Just as genes control the colour of your eyes or your hair, other genes control who is more likely to have allergies or asthma. We will examine genes and the expression of genes that allow some children to remain healthy while others get asthma or allergies.
- **Immune Factors:** The immune system is the part of the body that fights infections. We will use blood cells to study how the immune system relates to asthma and allergies.
- **Psychosocial Factors:** Using questionnaires and interviews, the CHILD Study will explore the thoughts, feelings, and experiences families have during and after pregnancy, and how they influence the well-being and health of children.
- **Environmental Factors:** Some environmental factors inside and outside our homes may affect children’s health and development, such as dampness and mould, chemicals used in flooring and furniture, cigarette smoke and pets. The CHILD study staff will visit your home to make observations and to collect a sample of dust.

Who can participate in the study?

You can participate in the study if you are a pregnant women over the age of 18, planning to deliver at Mount Sinai Hospital or Sunnybrook Health Sciences Centre and able to read and speak English. You should not participate in the study if you are pregnant with more than one baby, have had in vitro fertilization for this pregnancy or if your baby has evident health problems at birth or is born prematurely. You and your baby can participate in the CHILD Study whether or not you are in a relationship with the father of the baby.

Overview of The CHILD Study and your involvement

This chart summarizes the study from your pregnancy until your child is 5 years of age. We recognize the value of your time, and we will make every effort to minimize the length of your visits with us. Some of the questions are personal. We respect your privacy, so please only answer the questions you are comfortable answering.

Visiting Time	Location	Activity	Time Required for Visit
During Pregnancy (Mother and Father)	In clinic	Meet your CHILD research staff, complete questionnaires at home, minor medical test	1.5 hours over 20 weeks (Mother)
			45 minutes (Father)
When your baby is born	In hospital	Cord blood sample, lung inflammation test (baby)	15 minutes
2-4 Months	Home Visit/Clinic	Questionnaires, sample collection and home environment assessment Breathing tests in clinic (baby)	2 hours for home visit
			3 hours for breathing tests
9-12 Months	In clinic	Questionnaires, minor medical tests (Mom) Breathing tests and sample collection (baby)	3 hours
18-21 months	In clinic	Breathing tests (baby)	3 hours
6 months, 1.5, 2 years	Telephone or email	Update on your child's health	30 minutes
3, 4 and 5 years	In clinic	Questionnaires Breathing tests, sample collection (baby)	2 hours
Birth until 1 Year	In home	We will come to your home for a nasal swab when your child has a cold	15 minutes
Total time required over 5 years			23-25 hours

At Mount Sinai Hospital or Sunnybrook Health Sciences Centre

During pregnancy:

At approximately 4-5 months into your pregnancy we will ask you and the father of your child (if available) to come to the clinic to meet with our research staff. We will do the following:

Mother:

- Questionnaires: We would like to ask you questions about your general health, medications, diet, life stress, home environment and daily activities.
- Blood Sample: We would like to take a small blood sample (1.5 tablespoons) to look at genes and immune and dietary factors which may be related to allergy and asthma.

Father:

- Questionnaires: We will ask you questions about your general health, breathing and colds.
- Breathing Test: The breathing test is called "spirometry" and measures your lung function. By testing how much and how fast you can blow out, we can see how well your lungs work. These tests are routine in clinics and doctors' offices.
- Allergy Test: This test is used to see if you are allergic to foods, pollens, pets, mould or other environmental substances. We place 16 separate drops of clear liquid on your forearm, each one containing something we want to test, such as grass or cat hair (allergens). A very light pinprick of the skin is made through each drop. This may cause mild irritation, such as itching, if there is a response, but this settles within an hour. These tests are routinely done in clinics.
- Blood Sample: We would like to take a small blood sample (1.5 tablespoons) to look at genes and immune factors which may be related to allergy and asthma. If it is not possible to obtain blood, we will ask you for a saliva sample for genetic testing only.

At 36 weeks of pregnancy:

- We will give Mother her questionnaires to ask how you are feeling and how things are going in your life that may cause stress. These questionnaires will take about 15 minutes.

When Your Baby is Born

Mother:

- We will ask you to page the research team when you are ready to go to the hospital to deliver your child.
- After delivery, we will obtain information about your baby from the hospital record including the details of the delivery, medications used, and your child's weight and length.

Child:

- We will take 2-4 tablespoons (up to 60 mL) of blood from the umbilical cord after the baby is delivered. This blood would normally not be used for anything, but can be used to look at your child's immune system, and the different genes that might relate to allergy and asthma.
- A sample of meconium (first stool) will be collected to look for substances that your baby may have been exposed to during pregnancy, such as allergens or chemicals.
- Lung Inflammation Test: We may also perform a lung inflammation test on your baby before you are sent home from the hospital. To measure lung inflammation, we will measure Nitric Oxide (NO) levels in your child's breath. NO is a naturally occurring chemical that is increased when people have airway inflammation. This simple test is done by having your child breathe normally while resting or sleeping. The baby will continue to sleep with a mask on their face to collect the

air they breathe out. There is no risk to your child. This procedure should take 15 minutes.

Please note: There will be no tissue or blood samples taken directly from your baby at birth for this study. At no time is there any risk to your baby.

Home Visit: At 2-4 months

Our hospital research staff will contact you by phone to arrange a time to come to your home at your convenience for a one time home visit and home environmental assessment. At this time we will do the following:

Mother:

- Questionnaires: We will ask you questions about your baby's health, what your baby eats, any illnesses they have experienced, and where your baby spends his/her time.
- Breast Milk Sample: If you are breastfeeding, we would like to collect a sample of breast milk to look for factors that may affect your baby's immunity and health. We will provide you in advance with a container for collection. If you are not comfortable or able to provide a breast milk sample, this is not a problem.

Child:

- Urine Sample: We will ask you to place four cotton make-up pads, which we will supply, in your baby's diaper to collect a urine sample. Urine may help detect different environmental exposures, and early evidence of allergy or inflammation.
- Stool Sample: We will ask you to save the last diaper with your baby's stool. We want to look at what natural intestinal bacteria your baby has which may stimulate their immune system.
- Nasal Swab: We will use a moistened soft Q-tip-like swab to lightly dab inside the edge of your baby's nose. This will be used to see what viral infections your baby may have experienced.

Home Environmental Assessment:

We will ask you about your indoor environment including information about the construction, age and condition of your home. Sometimes we may want to take a picture of a housing element for the purpose of analysis. If this happens, we will ask your permission.

The research coordinator will do a home environment assessment that includes dust sampling for some allergens and pollutants, vacuuming from your baby's sleeping area (bed and floor), and the floor of the most commonly used living room.

AT THE HOSPITAL FOR SICK CHILDREN

Hospital Visit at 2-4 months of age:

We will invite you and your child to come to The Hospital for Sick Children to meet with our research staff. At this visit, we will take some height and weight measurements of your child and ask you to answer some questions and do some tests as follows:

Child:

- **Lung Inflammation Tests:** This is the same test that was done at birth. This simple test is done by having your child breathe normally while resting or sleeping. The baby will continue to sleep with a mask on their face to collect the air they breathe out. The sample of air tells us whether there is any inflammation in your child's lungs by measuring Nitric Oxide (NO) in the breath. There is no risk to your child. This procedure should take 10 minutes.
- **Breathing Test:** This is done while your baby is sleeping. We will work with you to organize the test to be done during your baby's regular nap time. To help your baby sleep during the test we will give your baby a sweet tasting syrup called chloral hydrate. When your baby is asleep he/she will breathe into a face-mask that is attached to a computer. With this computer we can measure how fast your baby is breathing, his/her oxygen and carbon dioxide level and his/her ability to blow air out of his/her lungs. Most babies will fall asleep easily with the chloral hydrate and will sleep for about 1-2 hours then wake up and have a normal meal. Some babies do not like the taste of the syrup and will spit it out, while other babies may snore. If their snoring is significant, we may have to take some extra precautions such as repositioning them or giving oxygen via a face-mask so this is no longer a problem. Once the babies wake up, their oxygen and carbon dioxide levels will return to normal. In another part of the test, your baby will breathe in some special gases that will help to determine if he/she has any early signs of wheezing problems. These special gases are odourless and have no known side-effects, they are called "inert" gases since they are not absorbed when we breathe them in and are breathed out naturally. If your baby sleeps long enough a mist of Ventolin® will be given to assess for any improvement in their breathing. This substance is routinely used in asthma clinics. This test may be useful to your child if he/she develops wheezing in the future, as it may serve as a baseline measure of their breathing status. If you would like to know more about this test, we can arrange for the respiratory therapist from the Infant Pulmonary Function Lab at The Hospital for Sick Children to speak with you. This test is done routinely in this hospital for babies with chronic breathing problems.
- **Urine sample:** We will provide 4 cotton makeup pads for you to place in your baby's diaper in order to collect a urine sample.

Visits for Viral Illness:

Most young infants will experience at least 2-3 colds in their first year of life with noticeable symptoms. It is important for us to know the types of respiratory illnesses your baby is exposed to in the first year of life, and so we would like to ask for your help in keeping track of your child's illnesses. We encourage you to call us when your baby is experiencing any signs or symptoms of viral infection or cold. When you call, we will ask you a series of questions about your baby's breathing and cold symptoms. If your baby is having a lot of symptoms, we will ask you if we can come into your home and obtain a nasal swab from your baby. These samples will be tested for viruses that may help us learn more about the development and course of allergies and asthma in children.

- **Nasal Swab:** We will collect a nasal swab by lightly dabbing a moistened, soft Q-tip-like swab inside the edge of your baby's nose. This will be used to see what infections your child may have recently had.

By Email: At 6 months of age:

We will email you to ask about your your baby's health, diet, breathing, environment, life stress and update contact information.

Clinic Visit: At 9-12 months

We will ask you and your child to come to the clinic and meet with our research staff. At this visit, we will take height and weight measurements of your child, use questionnaires to ask for similar information as asked at previous visits or telephone calls, and so some specific tests:

Mother:

- **Breathing Test:** The breathing test (spirometry) is performed. This is described on page 4
- **Allergy Test:** Skin allergy tests are performed. These are described on page 4
- **Blood Sample:** We would like to take a small blood sample (1.5 tablespoons) to look at genes and immune factors which may be related to allergy and asthma.

Child:

- **Urine Sample:** We will ask you to place four cotton make-up pads, which we will supply, in your child's diaper in order to collect a urine sample.
- **Stool Sample:** We will ask you to save and bring the last diaper with your child's stool.
- **Nasal Swab:** We will use a moistened soft Q-tip-like swab to lightly dab inside baby's nose.
- **Allergy Test:** Your child will have a skin prick test to look for allergies to foods or other environmental substances such as pets and pollens. 12 separate drops of clear liquid will be placed on your child's forearm. Each drop contains something different we want to test such as grass or food. A very light pinprick of the skin is made through each drop. This may cause mild irritation, such as itching, if there is a response but this settles within an hour. We will apply a cream to help ease any irritation. These tests are routinely done in clinics.
- **Blood Sample:** We would like to take a small sample of blood (2 teaspoons) to measure your child's immune response. We understand that this can be stressful for you and your child and will take every effort to make your child comfortable. We will use an anaesthetic cream to "numb" the skin, which makes the needle virtually painless.
- **Lung Inflammation Test:** We will measure Nitric oxide (NO) as a marker of airway inflammation as we have done at the birth and 3 month hospital visit. Your child will continue to breathe normally through a facemask attached to a computer. This test will take 10 minutes.
- **Breathing Test:** We would like to repeat the baby breathing test while they are sleeping as done at 2-4 months. This may be helpful to your baby if he/she has developed any wheezing symptoms or if they develop them in the future. Again, we are happy to share the results of this test with you and your family doctor.

By Mail: At 18 months, 2 years, 2 ½ years, 3 ½ years, and 4 ½ years

We will mail you questionnaires to ask about your child's health, diet, breathing and environment.

Clinic Visit: At 18 – 21 months of age (Hospital visit)

Tests for your child at 18-21 months will include allergy skin prick tests, as done at 9-12 months, collection of a small urine sample, and lung inflammation test and breathing test as done at 9-12 months. There is no blood test at 18-21 month visit.

Clinic Visit: At 3 and 4 years

We will ask you and your child to come to the clinic and meet with our research team. At this visit, we will take height and weight measurements and perform breathing and allergy tests with your child. We

will ask mother questions similar to previous visits, regarding your child's health, diet, medications, colds and breathing, and questions about any changes in your environment.

Tests for your child at 3 and 4 years will include allergy skin prick tests, as done at one year, collection of a small urine sample, and breathing tests (simplified spirometry as done by mother and father). There is no blood test at 3 or 4 years.

Clinic Visit: At 5 years

We will ask that you and your child come to the clinic and meet with our research team. We will take height and weight measurements of your child, ask you questions and do tests similar to those at the one and three year visits. We would like to do a different breathing test with your child which involves blowing out hard after breathing a number of salty mist solutions. We would also like to take a small blood and urine sample from your child.

Mother:

- Questionnaires: We will ask you questions about your child's health, diet, medications, colds and breathing symptoms. We will also ask you questions about your home environment and about places your child spends his/her time.

Child:

- Allergy Test: Your child will have allergy skin prick tests as at ages one and three.
- Urine Sample: We will provide a container for you to collect a sample of your child's urine.
- Blood sample: We would like to take a small blood sample (1-2 tablespoons) to look at the genes and immune and dietary factors we think may be related to allergy and asthma. We will use an anaesthesia cream to "numb" the skin, which makes the needle virtually painless.
- Breathing Test: The "methacholine challenge" test looks for evidence of asthma by measuring whether the airways in the lung narrow very easily. Your child will breath in a fine mist containing a very low concentration of methacholine, which is related to acetylcholine, a natural chemical produced in our bodies. We measure their breathing by spirometry, then gradually increase the level of methacholine in each mist and measure breathing after each mist. Sometimes during the test, children can get wheezy. If this happens, an asthma inhaler like Ventolin®, will be used to stop the wheezing within a few minutes. The test takes 30-45 minutes. This test is routinely done in many clinics.

The total time commitment for this study during pregnancy and over the five years of follow-up will be approximately 23- 25 hours.

Long-term follow-up:

Researchers involved in this study may be interested in longer term follow-up after the five year time period, and you may be asked about your interest in participating in additional studies in the future. There is no obligation to participate in any future studies, if you participate in the CHILD study.

Additional Contacts: You will be asked to list contact people (such as grandparents, other family or friends) for the purpose of contacting you if we cannot locate you – if you move or your number has changed.

OTHER STUDY CONSIDERATIONS

Voluntary Participation/Withdrawal from the study:

Taking part in this study is voluntary. If you enroll in the study and later change your mind, you can withdraw at any time and for any reason simply by contacting the research coordinator listed on this consent form. Withdrawal will not affect your baby's health care in any way. You may also choose not to answer some of the questions or participate in a particular test, and still remain in the study. You have the option of asking that your data are removed from the study.

Can I be asked to leave the study?

The doctors running this study may also decide that it is best that you/your child leave the study and will withdraw you/your child. This could happen if your baby is born earlier than 35 weeks or if you move away.

Potential Benefits:

There is no direct health benefit for you/your child from taking part in this study. However, your participation in this study may help other children born in Canada in the future who may suffer from allergy and asthma, or other conditions related to environmental exposures.

To Individual Subjects:

We cannot promise any personal benefits to you from this study other than a regular check on your child's health and early intervention should a health issue be discovered.

To Society:

Your participation may help other children born in Canada who may suffer from allergy and asthma by helping us understand the possible causes and factors that contribute to the development of these problems. This important information will help guide strategies to treat asthma better early in infancy.

Potential Risks and Discomforts

- **Questionnaires:** We will ask questions about how things have been going for you and your family since your pregnancy began. You do not have to answer any questions that you do not feel comfortable with. Everything that you talk about is completely confidential.
- **Baby Breathing Tests:** Baby breathing tests done at age 2-4 months, 9-12 months and 18-21 months involve the use of syrup called chloral hydrate to help them nap so we can do their test. Some babies will fall asleep and snore and may have a mild drop in their oxygen level or rise in their carbon dioxide level. If this happens, we will adjust your babies sleeping position and give them some extra oxygen or help them lower their carbon dioxide level until they are finished their nap. Occasionally, some babies may become more active instead of falling asleep. Many children and adults with and without asthma and allergies have had these tests in the past without having any problems.
- **Breathing Tests:** The risks associated with breathing tests for 3, 4, and 5 year olds are very small (lightheadedness or coughing). These tests are commonly used to diagnose and assess people with asthma. The methacholine test is done routinely in hospital clinics. Some children get wheezy during the methacholine test. If this happens, we stop the test and make sure your child's breathing is back to normal by giving an asthma puffer such as Ventolin®, which works in 2-3 minutes.
- **Blood Samples:** Drawing blood may cause some pain and carries a small risk of bleeding, light

headedness, bruising, and/or infection (less than 1% of patients experience it) at the site where the blood is drawn. We also understand that this can be quite stressful for a child and we will minimize the discomfort by using a numbing cream on the skin.

- **Allergy Tests:** Allergy skin prick tests are done routinely in clinics. The risk of a significant allergic reaction is extremely low. Any itchiness goes away in less than 1 hour.

In Case You Are Harmed In This Study

If you or your child are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. Signing this consent form in no way limits you or your child's legal rights against the sponsor, the investigators or anyone else. If you or your child becomes injured or unexpectedly ill as a consequence of participation in the study due to a study procedure, your medical condition will be evaluated and medical care will be provided by one of the investigators or you will be referred for appropriate treatment.

Reimbursement for Participation:

Your participation in this research project will not involve any additional costs to you or your health care insurer. We will pay your direct costs including travel and parking. In addition, we will compensate you \$100 for the time you commit to each one of the seven major assessments – during pregnancy, the home visit at 2-4 months, and the clinic visits at 3 months, 9-12 months, 18 months, 3 and 5 years – for a potential total compensation of \$700.

CHILD Study's Commitment to Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your name, address, date of birth, new or existing medical records that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 25 years. Only the study team will be allowed to contact you during the study. However, study sponsors, some management members of the CHILD Study national coordinating staff in Hamilton, representatives of the Mount Sinai Hospital, Sunnybrook Health Sciences Centre or the Hospital for Sick Children's Research Ethics Board, and representatives of Health Canada may review participants data to ensure that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

Study Information That Does Not Identify You

We will store information in a nationwide database, and will assign a study identification number (ID) to your name. Your name will be kept in a secure place, separate from your file labeled only by your ID number. Only CHILD study team members can access your personal data. The data collected will be used for this study and will be kept for 25 years or as long as required then destroyed as required by Mount Sinai Hospital, Sunnybrook Health Sciences Centre and Hospital for Sick Children unless you give permission as to retain data and samples long term. Computer information will be password protected.

Data security and confidentiality will be maintained with respect to the transmission of data via the Internet through the use of protective firewalls, security systems, encryption, secret passwords and special procedures that block unauthorized users. Personal study information from participants will be stored in a separate database that has no connection with the Internet and is also protected by a

firewall. If you choose to participate in this study, your personal health record may need to be reviewed by research staff in order to determine your eligibility and suitability for enrolment.

The Hospital for Sick Children will ask you for permission to link your and your child's health card number to a database housed at the Institute of Clinical and Evaluative Sciences (ICES). ICES is named in Ontario's Health Card and Numbers Control Act (1991) as the institution responsible for collecting health card numbers and related health information to be used for health services research and other epidemiological studies. The information obtained can include such things as your child's visits to doctors or outpatient clinics, new hospital or emergency department admissions, other tests and procedures, or the types of medications or health care services that were arranged for your child after his/her primary care visits. We would like to have access to information relevant to the study for up to 25 years. ICES scrambles your and your child's health card information in such a way as to make it impossible to identify the original number; thus ensuring that unauthorized personnel will not be able to link the health information with any individual.

Sample Storage and Analysis

For this research project, samples of blood from the mother, and from the father (if available), together with other biological samples (nasal swabs, urine, meconium, stool) from the infant, and samples of dust obtained from the home, are essential parts of the study. These samples will be labeled by a unique number so as to not identify you or your child. Some samples will be shipped to other specialized laboratories elsewhere in Canada, or in some cases the United States of America. Analyses of these samples, including DNA testing, allow us to understand the effects of both genetics and the environment on the development of the child.

Some testing may be deferred for months or even years until a later stage of the study, and until that time the samples must be securely stored. By participating in the CHLD study you give permission for storage of these samples for an indefinite period until we conduct all of these pre-planned analyses.

Samples and data will be held as long as the Principal Investigator of the CHLD study, his successor(s) and the Executive Committee can guarantee their proper management.

Due to the experimental nature of the planned analyses, it will not be possible to inform you, or the father of your child, or your own doctors, of the results of any tests, including genetic tests, on your samples.

You will have access to the general results of the study, including analyses of samples and data, as the analyses are reported in the medical literature, as we will keep you informed of publications arising from the research.

There are a couple of exceptions to confidentiality. The first is that if you tell research staff that you are planning to hurt yourself or someone else, the staff are bound by law to report that to the proper authorities. Second, if you tell research staff about any kind of child abuse, the staff are bound by law to report that to the proper authorities.

When the results of the study are published, your name will not be used and no information that discloses your identity will be released or published.

Are there any situations where a researcher will give information about me or my family to someone who isn't involved in the study?

We will respect your privacy. Published study results will not reveal your or your child's identity. No information about who you are (your child is) will be given to anyone or be published without your permission, unless required by law. We are obligated by law to report information about you to relevant authorities, if it is suspected at a clinic or home visit that your child has been abused or neglected.

Conflicts of Interest:

The investigators involved in this study do not have any conflicts of interest.

Questions:

If I have any questions or problems, whom can I call?

If you have any questions about the research, please contact Dr. Mathew Sermer (Mount Sinai Hospital) at: 416-586-4800 ex 8411, Dr. Elaine Herer (Sunnybrook HSC) at 416-971-6020 or the CHILD Study Clinical Research Nurse Coordinator, Karen McLean at: 416-813-7654 ext. 28077.

At the Hospital for Sick Children you may contact Dr. Padmaja Subbarao at: 416-813-2196, or the Clinical Research Nurse Coordinator Karen McLean at: 416-813-7654 ext. 28077.

If you have any questions regarding your rights as a research participant, whom do I call?

If you have any questions regarding your rights as a research participant, you may contact Dr. R. Heslegrave, Chair of the Mt. Sinai Hospital Research Ethics Board at 416-586-4875, Dr. Philip Hébert, Chair of the Sunnybrook HSC Research Ethics Board at 416-480-6100 ext 4276 or Mr. Richard Sugarman, Chair of the Research Ethics Board at the Hospital for Sick Children at 416-813-5718.

CONSENT STATEMENT (MOTHER and CHILD)

RESEARCH STUDY: The Canadian Healthy Infant Longitudinal Development (CHILD) Study

INVESTIGATORS: Dr. Mathew Sermer, Dr. Elaine Herer, Dr. Padmaja Subbarao, Dr. Malcolm R. Sears

SIGNATURE OF PARENT (Mother)

- I have read and understood the study information and this consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary. I have had the opportunity to ask questions, and had satisfactory answers to my questions.
- I understand the possible harms and benefits (if any) of this study
- I understand that all the information collected will be kept confidential, and that the results will only be used for scientific purposes.
- I freely give consent and understand that my/my child's participation in this study is voluntary and that I can withdraw later without any effects on my current or future medical care.
- I understand that I am not waiving any of my/my child's legal rights as a result of signing this consent form.
- I have been told that I will receive a dated and signed copy of this consent form for my own records.
- I authorize the CHILD study team to get in touch with alternate contacts that I will be providing in the event that I cannot be easily contacted over a 2 week period prior to my expected assessment.
- I understand I will give my health record number to link to provincial data.
- I agree to have my samples stored, identified on the label by ID number only, for an indefinite period of time for preplanned CHILD study analyses, including DNA testing.

Printed Name of Mother

Mother's signature

Date

Printed Name of person who explained consent

Signature of person who explained consent

Date

Principal Investigator Printed Name

Principal Investigator signature

Date

CONSENT STATEMENT (FATHER)

RESEARCH STUDY: The Canadian Healthy Infant Longitudinal Development (CHILD) Study

INVESTIGATORS: Dr. Mathew Sermer, Dr. Elaine Herer, Dr. Padmaja Subbarao, Dr. Malcolm R. Sears

SIGNATURE OF PARENT (Father)

- I have read and understood the study information and this consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary. I have had the opportunity to ask questions, and had satisfactory answers to my questions.
- I understand the possible harms and benefits (if any) of this study
- I understand that all the information collected will be kept confidential, and that the results will only be used for scientific purposes.
- I freely give consent and understand that my/my child's participation in this study is voluntary and that I can withdraw later without any effects on my current or future medical care.
- I understand that I am not waiving any of my/my child's legal rights as a result of signing this consent form.
- I have been told that I will receive a dated and signed copy of this consent form for my own records.
- I authorize the CHILD study team to get in touch with alternate contacts that I will be providing in the event that I cannot be easily contacted over a 2 week period prior to my expected assessment.
- I understand I will give my health record number to link to provincial data.
- I agree to have my samples stored, identified on the label by ID number only, for an indefinite period of time for preplanned CHILD study analyses, including DNA testing.

 Printed Name of Father

 Father's signature

 Date

 Printed Name of person who explained consent

 Signature of person who explained consent

 Date

 Principal Investigator Printed Name

 Principal Investigator signature

 Date