



Study Title: The Canadian Healthy Infant Longitudinal Development (**CHILD**) Study

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The Allergy, Gene and Environment Network Centers of Excellence, Canada (AllerGen NCE)

How you can PARTICIPATE in THE CHILD Study

You are being invited to participate in a national research study that will involve up to 1,000 families in Edmonton and a total of 5,000 families from four regions across Canada; Edmonton, Vancouver, Toronto, and Winnipeg.

The title of the study is “The Canadian Healthy Infant Longitudinal Development Study”. We want to observe your child’s growth and development over five years. Research plays an important role in helping improve the health of future children. You can help make this happen.

Background:

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:

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 may help to make a healthy and safer environment in the future and improve the quality of life for all children. We are examining:

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- **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.

Childhood Sleep and Developmental Study

How and where your child sleeps may be important in how they grow and learn. We want to look at your child's sleep habits to see how this affects their learning and development, and how it relates to the development of asthma and allergies. Snoring children, and children who do not get enough sleep have been shown to do poorly in school, have attention deficit hyperactivity disorder (ADHD) symptoms, are more likely to be obese, and can suffer from high blood pressure. Sleep problems are more common among children with allergies and asthma. Environmental exposures such as cigarette smoke are more common in children who snore, and in children with allergies. Learning what good sleep habits are, and making a healthy sleep environment may help Canadian children learn and grow better. The sleep and developmental testing is optional and is only being offered to the Edmonton participants of the CHILD study. ***You can still join the CHILD study even if you do not want to take part in the sleep studies and developmental testing.***

Eligibility

You can participate in the study if:

- you are a pregnant women age 18 or older;
- you plan to deliver your baby in a participating hospital in Edmonton;
- you are able to read and speak English; and
- you are willing to provide cord blood

The father of your baby will be asked to participate in one main assessment at the beginning, and a health questionnaire at the end of the study. If he does not want to take part, or you are not in a relationship with the father of the baby, you and your baby can still participate.

You should not participate in the study if you are pregnant with more than one baby or have had in-vitro fertilization (IVF) to become pregnant. If your baby has severe health problems at birth or is born before 35 weeks, we may withdraw you from the study at that time.

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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 answer only the questions you are comfortable answering. Study visit questionnaires may be completed in the clinic, over the telephone at a time convenient for you, or taken home to complete and mail back.

Visit Timing	Location	Activity	Time Required for Visit
During pregnancy (mother & father)	In clinic	Meet CHILD research staff and complete questionnaires and minor medical tests	1.5 hours mother, 1 hour father
36 weeks	Telephone	Life Stress questionnaires	15 minutes
When your baby is born	In hospital	Delivery information, collect samples	30 minutes
3 months	Home visit	Complete questionnaires, collect samples, and assess home environment	2 hours
1, 3 and 5 years	In clinic	Complete questionnaires and tests, collect samples, developmental testing	2 – 3 hours
	At home	Sleep Study: In – home overnight monitoring of child sleeping using a small portable monitoring device	overnight
18 months, 2½, 3½, and 4 ½ years	Telephone call/mail out	Check in on child's health	30 minutes (2 hours total)
Every 3 months	Telephone call/mail out	2 short sleep study questionnaires every 3 months	10 minutes (2.5 hours total)
2 and 4 years	In clinic	Developmental Testing, questionnaires	1 hour
		Sleep Study: Additional sleep study will be requested ONLY if your child has an abnormal result on prior testing	overnight
Total time required over 5 years <i>(*Note: Overnight Sleep studies and developmental testing are optional)</i>			15 to 20 hours (plus overnights)

During 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. Some questionnaires may be completed by phone, or taken home and mailed back.

Mother:

- **Questionnaires:** We would like to ask you questions about your general health, medications, diet, life stress, home environment and daily activities.

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- **Blood Sample:** We would like to take a small blood sample (1-2 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 (1-2 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 contact Mother by telephone to ask how you are feeling and how things are going in your life that may cause stress. This call will take about 15 minutes.

When Your Baby is Born

Mother:

- We will ask you to notify the research team when you are ready to go to the hospital to deliver your child. Do not be upset if you forget as we also ask hospital admitting staff to watch out for you and contact us.
- 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.

Baby:

- 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.

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 3 months

We will telephone you to arrange a convenient time to come to your home for a one-time home visit. At this visit, we will complete the following:

Mother:

- **Questionnaires:** We will ask you questions about you and your baby’s health and medications, what your baby eats, any illnesses they have experienced, sleeping habits 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.

By Telephone: At 6 and 9 months of age

We will telephone you to ask about your baby's health, sleeping habits, feeding, breathing, environment, your life stress and to update or confirm your contact information.

Clinic Visit: At 1 Year

We will ask you and your child to come to the clinic to meet with our research team. 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 do 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 (1-2 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

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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 may use an anaesthetic cream to "numb" the skin, which makes the needle virtually painless.
- **Developmental testing:** We will test your child to see how they are learning and developing. This takes about 50-60 minutes to complete. It may be done at the clinic visit, just prior to the sleep test, or at another time convenient for you.

This visit will take about 2 - 3 hours

Sleep Study: We will ask that your child have an in-home sleep study using a small portable monitoring system. This system consists of a small portable device, sensors and close-fitting belts/cables that the study staff will show you how to safely apply to your child, and turn on before they go to sleep. The sleep recorder will collect data as your child sleeps in their own bed. The study staff will arrange for pick up of the equipment the next day.

By Telephone: At 18 months, 2 ½, 3½, & 4 ½ years

We will telephone you to ask about your child's health, diet, colds and breathing, environment and sleeping habits.

By Telephone: At 18 months, 21 months, 2 ¼, 2 ¾, 3 ¼, 3 ¾, 4 ¼, & 4 ¾ years

We will telephone you to ask about your child's sleeping habits and update contact information.

Clinic Visit: At 2 years

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

- **Developmental Testing:** We will test to see how your child is learning and developing as was done at the 1 year visit.
- **Sleep Study:** If your child showed any abnormal results through the sleep questionnaires or testing at the previous assessment, we may ask that your child do another in-home sleep study using a small portable sleep monitoring system.

Clinic Visit: At 3 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, sleeping habits, medications, colds and breathing, and questions about any changes in your environment.

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- **Tests for your child at 3 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 years. We will also see how they are learning and developing as with previous visits.
- **Lung Inflammation Test (eNO):** We may do an additional test to measure the Nitric Oxide (NO) levels in your child's breath. NO is a naturally occurring chemical that is increased when people have airway inflammation. This is done by having your child breathe normally through a mask attached to a machine for about 10 seconds. The air from your child's breath tells us if there is any inflammation in your child's lungs. This regular clinic procedure takes about 10 minutes to complete, and there is no risk to your child.
- **Sleep Study:** We will ask that your child have an in-home sleep study using a small portable monitoring system as at previous visit(s).

This visit will take about 2 - 3 hours

Clinic Visit: At 4 years

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

- **Developmental Testing:** We will test to see how your child is learning and developing as done at previous visits.
- **Sleep Study:** If your child showed any abnormal results through the sleep questionnaires or testing at the previous assessment, we may ask that your child do another in-home sleep study using a small portable sleep monitoring system.

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, sleeping habits, medications, colds and breathing symptoms. We will also ask 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 may use an anaesthesia cream to "numb" the skin, which makes the needle virtually painless.
- **Lung Inflammation Test (eNO):** We may do this additional breathing test to measure the Nitric Oxide (NO) levels in your child's breath as was done at the 3 year visit.
- **Breathing Test:** The "methacholine challenge" test looks for evidence of asthma by measuring

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whether the airways in the lung narrow very easily. Your child will breathe 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.

- **Developmental testing:** We will test your child to see how they are learning and developing. This takes about 50-60 minutes to complete and will be done at the clinic visit, just prior to the sleep test, or at another time convenient for you.

This visit will take about 2 - 3 hours

Sleep Study: We will ask that your child have an in-home sleep study using a small portable monitoring system as done in previous visits.

The total time commitment for this study during pregnancy and over the five years of follow-up will be approximately 15 - 20 hours, plus overnight monitoring.

Long-term study 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 enrol 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. If you decide to withdraw, we will not include you in follow-up data collections and will only use data you provided to us during your participation.

The CHILD team may withdraw you from this study in some circumstances, for example, if you move away and cannot complete enough of the study visits.

Benefits:

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

We will provide you or your child's physician with results from the sleep studies and child development testing. This testing may help identify any early sleep, development or learning problems that you can explore with your child's doctor as necessary.

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.
- **Breathing Tests:** The risks associated with breathing tests 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.
- **Sleep Study:** Your child may experience difficulty falling asleep, or may not be able to tolerate or complete the sleep testing. Instructions for proper and safe set-up of the sleep equipment will be provided by the study staff.

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 (Gift card or cheque) for the time you commit to each one of the five major assessments – during pregnancy, the home visit at 3 months, and the clinic visits at 1, 3 and 5 years – for a total compensation of \$500.

Important Information Regarding the Storage of Blood and Other Samples:

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. The CHILD Study plans to use these samples to evaluate how environmental and genetic factors may affect children's health and development, including asthma and allergic diseases. The samples will be labelled by a unique number so as to not identify you or your child. They will be kept frozen at a secure central CHILD study storage facility located at the Clinical Research and Clinical Trials Laboratory at Hamilton General Hospital, 237 Barton Street E., in Hamilton, ON. Some samples will be shipped to other specialized laboratories elsewhere in Canada, or in some cases the United States of America for

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testing. 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, for testing of factors that may become important as we learn about them in the future and develop new methods of testing. By participating in the CHILD study you give us permission for storage of these samples for an indefinite period until we conduct analyses for purposes directly related to the CHILD Study.

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 we will keep you informed of publications arising from the research.

We would ask you to allow us to store your blood and biological samples, and the questionnaire and clinical data indefinitely for CHILD, for the purposes described above.

Confidentiality and Data Security:

Personal health records relating to this study will be kept confidential. Any research data collected about you/your child (e.g. name, address, phone number, personal health number) will not identify you by name, only by your initials and a coded number. A list linking the number with your name will be kept in a secure place, separate from your file. Only study team members at your hospital can access your personal data. The data collected will be used for this study only and will be kept as long as required and then destroyed. Computer database information will be password protected.

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

Your name will not be disclosed outside the research clinic. Any reports published as a result of this study will not identify you by name.

For this study, the study doctor may need to access your personal health records for health information such as past medical history and test results. He/she may also need to contact your family physician and your other health care providers to obtain additional medical information. The health information collected as part of this study will be kept confidential unless release is required by law, and will be used only for the purpose of the research study. By signing the consent form you give permission to the study staff to access any personally identifiable health information which is under the custody of other health care professionals as deemed necessary for the conduct of the research or to confirm your eligibility and suitability for enrolment.

In addition to the investigator(s) and the sponsor representatives (CHILD national study staff), the Health Research Ethics Board may have access to your personal health records to monitor the research and verify the accuracy of study data.

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By signing the consent form you give permission for the collection, use and disclosure of your medical records. At the University of Alberta, study information is required to be kept for 7 years after study completion. Even if you withdraw from the study, the medical information that is obtained from you for study purposes up to this point will not be destroyed. You have the right to check your health records and request changes if your personal information is incorrect.

Study Contact Names and Telephone Numbers:

If you have concerns about your rights as a study participant and you are participating at a Capital Health facility, you may call the Patient Relations Office of Alberta Health Services at 780-342-8080. If you are participating at a Covenant Health hospital, you may call the Covenant Health Research Centre at 780-735-2274. These offices have no affiliation with the study investigators.

Please contact any of the individuals identified below if you have any questions or concerns:

Dr. Piush Mandhane, Assistant Professor

Name and title

780-407-3302

Telephone Number

Deanna Gilbert, Research Coordinator

Name and title

780-407-8084

Telephone Number

CONSENT FORM

Title of Project: **The Canadian Healthy Infant Longitudinal Development (CHILD) Study**

Principal Investigator(s): **Dr. Piush Mandhane**
Research Coordinator(s): **Deanna Gilbert**

Phone Number(s): **780-407-3302**
Phone Number(s): **780-407-8084**

(To be completed by the research subject):

Yes **No**

Do you understand that you/your child have been asked to be in a research study?

Have you read and received a copy of the attached Study Information Sheet?

Do you understand the benefits & risks involved in taking part in this research study?

Have you had an opportunity to ask questions and discuss this study?

Do you understand that you/your child are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?

Has the issue of confidentiality been explained to you?

Do you understand who will have access to you/your child's records, including personally identifiable health information?

Do you want the investigator(s) to inform your family doctor that you are taking part in this research study? If so, give his/her name: _____

Do you agree that you/your child's biological samples be stored for pre-planned CHILD Study analyses (eg. Genetic testing, environmental toxins)

Who explained this study to you? _____

I agree to take part in this study: **YES** **NO**

Signature of Research Subject: _____

(Printed Name): _____ Date: _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of person explaining and obtaining consent: _____

Printed name and role: _____ Date: _____

Signature of Investigator or Designee: _____ Date: _____

**THE STUDY INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM
AND A COPY GIVEN TO THE RESEARCH SUBJECT**