



The Canadian Healthy Infant Longitudinal Development (CHILD) Study

INVESTIGATORS AND FUNDING PARTNERS

Protocol number: H2007:255

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Funding Partners: Canadian Institutes of Health Research (CIHR)
 The Allergy, Genes and Environment Network of
 Centres of Excellence (AllerGen NCE), Canada
 Childhood Asthma Foundation
 Health Canada
 Environment Canada
 Canada Mortgage and Housing Corporation

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Participant’s No _____

Participant’s Initials _____

HOW YOU CAN PARTICIPATE IN THE CHILD STUDY

You are being invited to participate in a national research study which will involve up to 1,500 families in Manitoba and a total of 5,000 families from four regions across Canada.

The title of the study is “**The Canadian Healthy Infant Longitudinal Development Study**” or CHILD. 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.

We would like you to take the necessary time to understand what is involved with this study including the benefits and any potential risks, and to discuss the study with your family, friends and family physician if you wish. We are available to answer any questions you may have.

Purpose of the CHILD Study

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.

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.

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Eligibility

You can participate in the study if:

- you are a pregnant women over the age of 18,
- you plan to deliver your baby in Winnipeg; and
- you are able to read and speak English.

The father of your baby will be asked to participate in just one assessment. If 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.

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.

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
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
6 months	Telephone call	Check in on child's health	30 minutes
1 year	In clinic	Complete questionnaires and tests, collect samples	1 hour
18 months, 2, 2½, 3½, 4 and 4 ½ years	Telephone call	Check in on child's health	30 minutes each
3 years	In clinic	Complete questionnaires and tests	1.5 hours
5 years	In clinic	Complete questionnaires and tests, collect samples	2 hours
Total time required over 5 years			12 hours

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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.
- 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 page 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 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.

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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 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.

By Telephone: At 6 months of age

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

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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 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.

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

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

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, medications, colds and breathing, and questions about any changes in your environment.

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.

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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 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 12 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.

Participant's No _____

Participant's Initials _____

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.

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.

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, lightheadedness, 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.

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 with \$100 in gift certificates 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 worth in gift certificates.

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CHILD STUDY'S COMMITMENT TO CONFIDENTIALITY

The CHILD Study is committed to the highest level of confidentiality for our participants. At all times, you and your child's confidentiality will be respected. Medical Records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. No information that discloses your identities will be released or published without your specific consent.

For this study, the study doctor may need to access your health records for information such as past medical history and test results. He/she may also need to contact your family physician and other health care providers to obtain medical information. The health information collected as part of this study will be kept confidential, unless release is required by law. Any information collected as part of this study will be used only for the purpose of this 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, necessary for the conduct of the research. No records which identify you or your child by name will be allowed to leave the CHILD Study offices.

We will request your personal health information number and your Manitoba registration number as well as your permission to link the information you provide to us with information about you and your child's doctor visits and hospitalizations (including service dates, diagnoses, procedures, and fees for services); prescription drug records (including service dates, drug names, amount provided), and records from your child's birth. This is done in order to better understand you and your child's health over time. The personal health numbers are used only for linkage. These data fields are removed from the research data and are stored separately in secure data facilities. The linked data will only be used for research or statistical purposes. All information is collected, used, and/or disclosed for research purposes, in strict agreement with the privacy information act.

If you are a research subject from St. Boniface General Hospital, your research related records may be reviewed by St. Boniface General Hospital for quality assurances purposes.

All personal information, such as your name, address, phone number, health insurance number, and family physician's name will be removed from the data we collect. We will store research information in a nationwide database, and will replace your name with a unique number. A list linking the number with your name will be kept in a secure place, separate from your file. The data collected will be used for this study only and will be kept for as long as required then destroyed as required by hospital policy. 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.

Participant's No _____

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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.

Inspection and/or copying your research records for quality assurance and data analysis:

For the purposes of ensuring proper monitoring of the research study, a member of the University of Manitoba Health Research Ethics Board, a Health Canada representative, or the CHILD national study staff may consult your research data and medical records. However, no records which identify you by name or initials will be allowed to leave the hospital. By signing this consent form, you or your legally acceptable representatives authorize such access.

HOW TO CONTACT THE WINNIPEG CHILD STUDY TEAM

If you have any questions about the research, please contact Dr. Allan Becker or the Research Coordinator, Rishma Chooniedass:

Dr. Allan Becker
504 John Buhler Research Centre
715 McDermot Ave
Winnipeg, MB R3E 3P5
Telephone: 787-2448
(24 hour contact: 952-2246)

Ms. Rishma Chooniedass
504 H John Buhler Research Centre
715 McDermot Ave
Winnipeg, MB R3E 3P5
Telephone 789-3978
rchooniedass@mich.ca

If you have any concerns about your rights as a research subject, and/or your experiences while participating in this study, contact The University of Manitoba Health Research Ethics Board at (204) 789-3389.

Participant's No _____

Participant's Initials _____

STATEMENT OF CONSENT AND AUTHORIZATION

It is important for you to know, that if you consent to take part in this study, although we would make every effort for you to be able to take part in all of the tests below, you can still take part even if you are unable to complete some of the visits or tests. Also, you can withdraw from this study at any time with no impact on the healthcare you will receive.

By signing this consent form you will allow the research staff to collect information from the mother's medical chart and the baby's medical chart. This will include the date of birth, ethnicity, gestation, type of delivery, length of labour, birth weight and length.

- 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 provide in the event that I cannot be contacted over a 2 week period prior to my expected assessment.
- I understand that I will give my health identification and registration number.
- I authorize the inspection of my medical research records by the University of Manitoba Health Research Ethics Board.
- 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 genetic testing.

Printed Name of Mother

Mother's signature

Date

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

Participant's No _____

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