Principal Investigator:

Dr. Stuart Turvey
Child & Family Research Institute
BC Children's Hospital
604-875-2345 ext 5094

Co-Investigators:

Drs. Tobias Kollmann and Michael Kobor
Child & Family Research Institute
BC Children's Hospital

Drs. Edith Chen and Greg Miller
Psychology
University of British Columbia

Dr. Michael Brauer
Occupation & Environmental Hygiene
University of British Columbia

Drs. Tim Takaro and Ryan Allan
Health Sciences
Simon Fraser University

Drs. Scott Tebbutt, Peter Parè,
iCAPTURE Laboratories
University of British Columbia

Dr. Peter von Dadelszen
Maternal Fetal Medicine
BC Women's Hospital

INFORMATION AND CONSENT FORM – **MOTHER & CHILD**

Title of Research Study:	The "**C**anadian **H**ealthy **I**nfant **L**ongitudinal **D**evelopment" (CHILD) Study
Principal Investigator:	Dr. Stuart Turvey Child and Family Research Institute BC Children's Hospital University of British Columbia (604) 875-2345 extension: 5094
National Principal Investigator:	Dr. Malcolm Sears St Joseph's Healthcare Firestone Institute for Health Research Hamilton, Ontario (905) 522.1155 extension 33286
Sponsors:	Canadian Institutes of Health Research (CIHR) and AllerGen NCE , Canada
Local Contacts:	Research Coordinator Department of Paediatrics, BC Children's (604) 875-2000 extension 6390
Emergency Contact:	For contact related to the study, please call: 604-977-9791. For medical emergencies, please contact your own Family Dr./Specialist

INVITATION

You are being invited to take part in this research study because you are pregnant and planning to give birth at this hospital. The title of the study is "the **C**anadian **H**ealthy **I**nfant **L**ongitudinal **D**evelopment" (CHILD). The following pages explain the study so you can make an informed decision about you and your baby taking part or not. A member of the study staff will talk to you about the details of the study and answer any question that you have. Please read this consent form carefully and take your time deciding.

YOUR PARTICIPATION IS VOLUNTARY

You/your child's participation in this study is entirely voluntary, so it is up to you as the guardian of your child to decide whether or not to take part. 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.

WHO IS CONDUCTING THE STUDY?

The study is being conducted under the leadership of Dr. Stuart Turvey a researcher and paediatrician at the BC Children's and Women's Hospital located in Vancouver. In addition to Dr. Turvey other researchers from the University of British Columbia, St. Paul's Hospital's iCAPTURE Laboratories and Simon Fraser University will be involved with the study. CHILD is a national research study directed by Dr. Malcolm Sears at McMaster University in Hamilton, Ontario.

The study is funded by The Canadian Institutes of Health Research and AllerGen NCE , Canada—The Allergy, Genes and Environment Network (Canadian federal granting agency).

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.

The CHILD Study will involve a total of 5,000 families (up to 15,000 subjects) across Canada, with 1,500 being recruited from Vancouver. Families (which can include the child, the father and the mother) will be recruited from Vancouver, Edmonton, Winnipeg and Toronto.

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 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 19.
- you plan to deliver your baby at BC Women's Hospital or St. Paul's Hospital.
- you are able to read and speak English
- willing to provide cord blood

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.

WHO SHOULD NOT PARTICIPATE IN THE STUDY? 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 (i.e. the medical process by which egg cells are fertilised by sperm outside the body). 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.

WHAT DOES THE STUDY INVOLVE?

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, Consent /Enrollment 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	10 minutes
3 months	Home visit	Complete questionnaires, collect samples, and assess home environment	2 hours
1 year	In clinic	Complete questionnaires and tests, collect samples	1-2 hours
6 months, 18 months, 2, 2½, 3½, 4 and 4½ years	Telephone	Check in on child's health	30 minutes each
3 and 5 years	In clinic	Complete questionnaires, tests, samples	1-2 hours
36 wks, 1 ,3 and 5yr	Telephone	Life Stress Interview	~ 1 hour each
Total time required over 5 years			**12-14 hours**

<u>During Your Pregnancy</u>

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 (3-4 teaspoons or 15mls) to look at genes and immune and dietary factors which may be related to allergy and asthma.

At 36 weeks of pregnancy:

- We will contact you by telephone to ask how you are feeling and how things are going in your life that may cause stress. We will ask if we can audiotape the call at the time we contact you and will only do so with your permission.

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.

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. All blood test results are reviewed by the study doctor, if there is any cause for concern you will be notified, along with your Family doctor.

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 three 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 study staff 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.

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 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 blood sample (3-4 teaspoons or 15mls) 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.

Child:

- Urine Sample: We will ask you to place three 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 similar to your test except using 12 separate drops instead of 16 drops of allergens.

- Blood Sample: We would like to take a small sample of blood (1 teaspoon) 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. Optional for child, we can apply a "numbing cream" to the arm before the blood sample is taken.

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). There is no blood test at 3 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 heath, 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 blood sample (1-2 teaspoons) to look at the
- genes and immune and dietary factors we think may be related to allergy and asthma. Optional for child, we can apply a "numbing cream" to the arm before the blood sample is taken.

- 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 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.

The total time commitment for this study during pregnancy and over the five years of follow-up will be approximately 12 -14 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.

WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

- 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 can offer to use a numbing cream on your child's arm to minimize discomfort.
- 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.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

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.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

If new information arises that may affect your willingness to remain in this study, you will be advised of this information promptly.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Taking part in this study is voluntary. You do not have to take part in this study. If you enrol you and your baby in this study and later change your mind, you can withdraw at any time and for any reason by contacting the Research Coordinator, Department of Paediatrics, at 604.875.2345 extension 6390. Withdrawal will not affect your baby's health care in any way. You may also choose not to answer all of the questions and still remain in the study. If you decide to withdraw from this study, we will not include you in follow-up data collections and will only use the data you provided to us during your study participation

WHAT HAPPENS IF SOMETHING GOES WRONG?

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. However, signing this consent form in no way limits your 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.

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 you move away or if you cannot follow the study plan.

AFTER THE STUDY IS FINISHED?

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. Dr. Stuart Turvey, as over-all investigator for the study can be contacted should you require information on the results of the study by calling 604.875.2000 local 5094.

Researchers involved in this study may be interested in follow-up after the five year time period, and participants may be asked in the future about their interest in participating in further study.

WHAT WILL THE STUDY COST ME?

Your participation in this research project will not involve any additional costs to you or your health care insurer. You will receive payment for parking at each visit. In addition, you will be compensated with a $100 grocery voucher 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 in grocery cards.

SAMPLE STORAGE

The samples that we collect from you and your child will be stored for purposes of analysis directly related to the CHILD Study. The CHILD Study plans to evaluate how environmental and genetic factors may affect children's health and development, including asthma and allergic diseases.

Biological samples will be collected and labelled by a number only so as to not identify you or your child. They will be stored frozen at a central storage facility for all CHILD Study samples 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 laboratories elsewhere in Canada.

PAST MEDICAL HISTORY AND TESTS

We will ask you to provide your own and your child's personal health number and personal education number, so that we can request information about you and your child from administrative and educational data sets under the stewardship of the British Columbia Ministry of Health Services, the British Columbia Ministry of

Education, the College of Pharmacists of British Columbia, the Vital Statistics Agency, and the Human Early Learning Partnership.

We will request linkage of 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), records from your child's birth, your child's developmental status as recorded by his/her kindergarten teacher, and other health related information, in order to better understand your own and your child's health over time.

We will request these data for the year prior to your first visit, through the five years that you are in the study, and for one year following your final visit. The data we collect in our study will then be combined with this information as described above. It is important for you to understand that this portion of the study is optional and that you may participate in the main portion of the study without providing this information. There is a check box on the signature page of this consent form which you can indicate your option to provide access.

The personal health number and personal education number 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 BC Freedom of Information and Privacy Protection Act (FIPPA).

WILL MY TAKING PART IN THIS STUDY BE DEPT CONFIDENTIAL?

Your/your child's confidentiality will be respected. No information that discloses your identities will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you/your child may be inspected in the presence of the Investigator or his or her designate, a representative of Health Canada and /or the UBC Research Ethics Boards for the purpose of monitoring the research. However, no records which identify you or your child by name will be allowed to leave the Investigators' offices.

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.

In rare instances it will not be possible to ensure confidentiality because of mandatory reporting laws. This legal obligation includes a number of circumstances, such as suspected child abuse and infectious disease, expression of suicidal ideas, where research documents are ordered to be produced by a court of law and where researchers are legally obliged to report to the appropriate authorities.

It is unusual to include information that would identify you or your child (e.g. the date of birth) on research records and material. We will store information in a nationwide database, and before storing it, will replace your name with a number. A list linking the number with your name, date of birth and personal health care number (PHN) will be kept in a secure place, separate from your file. The hard copy list with identifying information will be kept only in the local hospital office. Access to your data are through secure password protected database and limited to Vancouver CHILD Study coordinators and members of the management team at the National Coordinating Center in Hamilton for purposes of ethics approved newsletters, reimbursement and monitoring the quality of study data. The data collected will be used for this study only and will be kept as long as required then destroyed as required by the University of British Columbia's policies.

Your audio tapes will be kept digitally at the main University of British Columbia campus on a password-protected computer, accessible only to the Principal Investigator(s) and the members of their research team. All tapes will be identified by code number only.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions about the research now or think you have a research-related injury, please contact Dr. Stuart Turvey at (604) 875-2000 extension 5094 or the Research Coordinator at 604.875.2000 extension 7882.

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your rights as a research subject, and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services at 604-822-8598 or by email at RSIL@ors.ubc.ca.

In addition you may contact Dr. Hal Weinberg, Director, Office of Research Ethics, Simon Fraser University at 778.782.3447 or by email at hal_weinberg@sfu.ca regarding any concerns or complaints regarding the environmental home assessment visit.

If you need more information concerning this research you can contact the study coordinators or the investigators at the numbers provided on the front page of this document.

PI (Dr. Stuart Turvey) S. TURVEY

STATEMENT OF CONSENT AND AUTHORIZATION **Research Study: CHILD, Dr. Stuart Turvey**

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 subject 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 that all the information collected will be kept confidential, and that the results will only be used for scientific purposes.
- I understand that all interviews for the psychosocial factors will be audiotaped if I provide permission at the time of the interview.
- I understand that my/my child's participation is 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 freely consent to participate in this study.
- 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 agree to have my/my child's samples stored, identified only by an ID number for an indefinite period of time for preplanned Child study analysis only, including DNA genetic testing.
- I agree for this study, for designated study personnel to access my personal health records for health information such as past medical history and test results. ☐ **Yes** ☐ **No**
- I agree for this study, for designated study personnel to access my child's personal health records for health information such as past medical history and test results. ☐ **Yes** ☐ **No**

_____ _____ _____

Printed Name of Mother Mother's signature Date

Time of Signature: _____

_____ _____ _____

Printed Name Designated Study staff who explained consent Signature of Designated study staff Date

_____ _____ _____

Principal Investigator Printed Name PI signature Date