Institut de la statistique Québec

Family No.: ☐☐☐☐

I Am, I'll Be

Survey on the Future of a Generation

CHU Sainte-Justine
*Le centre hospitalier universitaire mère-enfant*
*Pour l'amour des enfants*

Université de Montréal

Douglas Institut universitaire en santé mentale / Douglas Mental Health University Institute

McGill

Université Laval

# Consent Form

**Québec Longitudinal Study of Child Development**
**QLSCD (E11) – Health Round 2008**



## 1. Title of the Study

The study entitled "I Am, I'll Be – Health Round" is a new round supplementary to the regular round of the survey. *Direction Santé Québec (DSQ)* (Health Québec Directorate) of the *Institut de la statistique du Québec (ISQ)* (Québec Institute of Statistics) is in charge of the project. The University of Montréal will supervise the data collection which will be conducted by registered nurses and research assistants. The *Bureau d'Intervieweurs Professionnels (BIP)* (Bureau of Professional Interviewers) will supervise communication with the 1,974 families that will be asked to participate in the data collection.

## 2. Names of the Researchers

Principal Researchers: L. Séguin, M.D.,MPH, University of Montréal; Richard E. Tremblay, PhD, University of Montréal.
Co-Researchers: G. Paradis, M.D., M.Sc., McGill University; T. Barnett, PhD. University of Montréal; M. Daniel, PhD, University of Montréal; E. Delvin, PhD, University of Montréal; L. Gauvin, PhD, University of Montréal; K. Gray-Donald, PhD, McGill University; J. Hanley, PhD, McGill University; M. Lambert, MD, University of Montréal; E. Levy, PhD, University of Montréal; E. Loucks, PhD, McGill University; S. Lupien, PhD, McGill University; J. Lynch, PhD, McGill University; J. McGrath, PhD, Concordia University; P. Newacheck, PhD, University of California; B. Nicolau, PhD, University of Québec/Institut Armand-Frappier; P. Poirier, MD, Laval University; M.-V. Zunzunegui, PhD, University of Montréal; G. Turecki, MD, PhD, McGill University; M. Boivin, PhD, Laval University.

## 3. Source of Funding

This project is funded by the Canadian Institutes of Health Research (CIHR) and the *Fonds de la recherche en santé du Québec (FRSQ)* (Québec Health Research Fund).

## 4. Invitation to Participate in a Research Project

The "health" round covers three main areas of research. The first consists of studying factors associated with stress and the risk of heart disease. The second consists of studying environmental health factors, such as those associated with the behaviours and development of children. The third consists of analyzing genetic factors related to the presence or absence of certain behaviours.

You and your child's longstanding participation in the QLSCD is a major asset for us in terms of achieving these objectives. This is why we are inviting you and your child to participate in the "health" round. It is not because we think your child has any behavioural or health problems that we are asking you to participate – all the families who have participated in the study since 1996 are being invited to participate, just like your family.

In addition, to fulfill its objectives, this round of the study requires biological samples (saliva and blood) from respondents. The bank of biological samples will be **strictly** used for scientific goals and has no commercial purpose. However, discoveries that may result from analyses of the data may give rise to patents having a commercial value from which the study participants will derive no financial benefit.

## 5. What is the Nature of this New "Health" Round

**After applying an anaesthetic cream** to minimize any discomfort, all the blood samples described below will be taken using the same catheter (flexible or not) inserted into a vein in the arm. Therefore, there will be **only one needle** for all the blood samples, for a maximum of 32 ml of blood (two tablespoons in five 6 ml tubes and two 2 ml tubes).

For the study of the risk factors of heart disease, a fasting (not having had anything to eat or drink since 10:00 pm the previous evening) blood sample will be taken in order to analyze the lipid (fat in the blood) level in the body and test the blood glucose level (sugar in the blood) and insulin level. The blood that is left over will be kept for future analyses related to the risk of heart disease. The cardiac rhythm (heartbeat) of your child will also be recorded using a small instrument called the Holter monitor that your child will wear without affecting his movements. In addition, anthropometric measurements of your child will be taken by the nurse – height, weight, waist, sitting height – as well as blood pressure (with a cuff on the arm). For the study of stress factors, you and your child will take yourselves a sample of your saliva for the analysis of the salivary cortisol (a substance found in saliva) in the week following the nurse's visit.

For the environmental health factors, the nurse will use one of the blood samples to conduct analyses of the presence of lead and for future tests of other factors related to health.

For the genetic factors associated with behaviours, the nurse will use one of the blood samples to extract genetic material. However, only for this line of research, the blood sample could be replaced by a taking a saliva sample during the visit. Visits that do not involve taking a blood sample will be conducted by a qualified research assistant. Besides the blood or saliva sample, an additional saliva sample will be taken to do epigenetic analyses. A comparison of the results of the epigenetic analyses of the blood and saliva will be conducted when all of the samples required for the analyses will have been taken.

## 6. Procedures During the "Health" Round Visit

If you accept to participate, the visit will take place at your home conducted by a registered nurse with identification from the *ISQ* and/or *BIP*. Here is a description of the procedures of the "health" visit upon which you will accept or not to have a blood sample taken:

### A) Signing the consent form

Upon her arrival, the nurse or research assistant will answer any questions you may have, and then you will sign two copies of the consent form. One will be given to the *DSQ* and you will keep the other for your files.

### B) Visit procedure

#### a) Visit with a blood sample, conducted by a registered nurse

**The "health" visit will be conducted in the morning and your child will have fasted (no food or drink) since 10:00 p.m. the night before.** First of all, the nurse will apply an anaesthetic cream to numb the skin where the blood sample will be taken in order to minimize any discomfort your child may experience. Then she will apply a Holter monitor to measure your child's cardiac rhythm. The nurse will then ask your child to rinse out his/her mouth to remove any food particles. She will then collect some of his/her saliva in a special container. She will then conduct anthropometric measurements and take the blood samples. All the samples will be taken using the same catheter (flexible or not) inserted into a vein in the arm. Therefore, there will only be one needle inserted for all the samples. She will then give breakfast to your child, and while he/she is eating, will conduct some tests on the samples. Once breakfast is finished, the nurse will give you your questionnaire (duration of approximately 25 minutes) and fill out one with your child (duration approximately 30 minutes). The nurse will also measure your child's blood pressure. She may have to measure the size of your child's arm in order to choose the right sized cuff. A research assistant may accompany the nurse in certain consenting families to repeat the blood pressure and anthropometric measurements.

#### b) Visit without a blood sample, conducted by a research assistant

**The "health" visit will be conducted in the morning and your child will not be required to have fasted since the night before.** To begin, the research assistant will apply a Holter monitor to measure your child's cardiac rhythm. She will then conduct anthropometric measurements. After that, she will give you your questionnaire to fill out (duration approximately 25 minutes) and will fill out one with your child (duration approximately 30 minutes). Once that is done, she will measure your child's blood pressure. She may have to measure the size of your child's arm in order to choose the right-sized cuff. After this, she will ask your child to rinse out his/her mouth to remove any food particles. She will then collect some of his/her saliva in two special containers. Another research assistant may be there during the visit in certain consenting families to repeat the blood pressure and anthropometric measurements.

### C) Conclusion of the visit (with or without a blood sample)

To conclude the visit, the nurse or research assistant will explain how to take the samples of salivary cortisol (saliva) in the week following the visit and answer any questions you may have. Once the sample kit has been given to you, she will remove the Holter monitor that measured your child's cardiac rhythm. If you request it, she will then give you the results of the measurements of your child's height, weight and blood pressure that were taken earlier.

The total duration of the visit with a blood sample should be about two and a half hours, while the visit without a blood sample should take about two hours.

### D) Procedure for taking the saliva samples for the analysis of the salivary cortisol after the "health" round visit

On the **Tuesday** and the **Thursday following the nurse's or research assistant's visit**, you and your child will take two samples each of your saliva on each of these days. The nurse or research assistant will explain this to you during her visit and answer any questions you may have. These samples should be taken after having fasted (no food or drink in the morning before taking them) – the first after waking up and the second 30 minutes later, still fasting. To take the sample, you and your child only have to spit into a saliva container up to the line indicated. The nurse or research assistant will give you the saliva containers during her visit. They will already be labeled for you and your child. Once you have taken the samples, you must place them in the kit and then put the kit in the freezer. A person from *BIP* will telephone you the evening before the sample days to ensure the procedure goes as planned. The Monday following taking the samples, you will put the kit in the prepaid, pre-addressed envelope designed for this purpose that had been given to you by the nurse. All you have to do is put it in the mail Monday morning. Someone from *BIP* will call you on the Monday evening to confirm that you mailed it.

## 7. <u>What Are the Benefits?</u>

If you like, the nurse or research assistant will give you the results of the height and weight measurements, and the blood pressure measurement (and what it indicates) conducted during the visit. Then, if you would like us to, we will send you the following results of the blood tests: **fat** (cholesterol and triglycerides) **and sugar**, with an interpretation of them. (At no time will we send you any genetic results). We will send you the blood test results by mail with a telephone number if you have any questions. You can show these results, whatever they contain, to your child's general practitioner or pediatrician. All the information collected, including the results of these tests, will be kept confidential. You may not see any immediate benefit in participating in this study, but these results can help the entire population of Québec in terms of designing better prevention programs and treatment for problems related to behaviours, stress, heart health and environmental health.

## 8. <u>What Are the Risks?</u>

Being informed of the results of the aforementioned tests can present certain risks for your family, such as perhaps causing anxiety or stress. The anthropometric measurements (height, weight, waist and sitting height) do not present any risk. Measuring blood pressure can cause mild discomfort (pressure from the cuff). The blood sample will be taken by a registered nurse. Sometimes this can cause mild bleeding, a bruise, dizziness, fainting (rare), an infection or discomfort in the region where the needle was inserted. To minimize discomfort that can be associated with a needle, the nurse will offer

you some cream for your child that can be applied to the skin to cause local numbness. Allergies to this cream are rare, but possible. The nurse will have received specific training to handle any discomfort or any known problem that can arise. Measuring your child's cardiac rhythm with the Holter monitor and taking saliva samples present no apparent risk.

## 9. Suspending Participation

At any time, the ISQ, the researchers, the nurse or research assistant can decide to end part or all of your participation in this health round if they deem it necessary for your health or the health of your child.

## 10. How Is Confidentiality Ensured?

The results of the research and all the information you provide to us is kept strictly confidential, unless you authorize otherwise or because of an exception in the law.

The blood or saliva samples are coded (i.e. given a number) by the nurse or research assistant at the time they are taken. The code and the initials of the child will be used when sending the samples to the laboratory for analysis, and all the laboratory technicians working on this study will have been sworn to confidentiality. It will be impossible to establish any link between the codes and your identity (name, address, telephone number) in the laboratories or research facilities. All the results of this study may be published or communicated in one form or another, but it will be impossible to identify the individual identity of your child because the analyses are always done on a group of subjects and not on individuals. Therefore, in this sense, the results are completely anonymous. Furthermore, it is impossible for personal results to be communicated to third parties (for example, employer, government department, insurance company, or school).

However, a lead level in the blood that surpasses normal values (0.48 µmol/litre) is considered a mandatory notifiable disease in Québec. If the laboratory finds a level of lead higher than this norm, they will notify the *DSQ* of the *ISQ*:

1. It is mandatory for the *DSQ* to notify you, even if you have refused to be given the results of the analyses.
2. It is also mandatory for the *DSQ* to give your name, address and telephone number to the *Direction de santé publique (DSP)* (Public Health Department) in your region. The *DSP* in your region will contact you in order to take steps towards finding the source of contamination and eliminate it, the goal being to protect the health of you, your child and your family.

To verify how the research is being managed, it is possible that a member of the Ethics Committee of the *ISQ* and/or the Research Ethics Committee of the Saint-Justine Hospital and/or the University of Montréal and/or the Douglas Hospital will examine the data of this "health" round, on a confidential basis. The questionnaires will be destroyed 10 years after the termination of the study.

## 11. Preserving and Managing the Bank of Biological Samples

The analyses of genetic factors (from the blood or saliva samples) related to behaviours and the measurement of salivary cortisol in the saliva will be conducted by the Douglas Hospital Research Centre in Montréal (Verdun) under the supervision of Dr Gustavo Turecki and Dr. Sonia Lupien respectively. The epigenetic analyses (blood or saliva) related to behaviours will be conducted by the McGill University in Montréal under the supervision of Dr Moche Szyf. The heart health analyses (from the blood sample) will be conducted at Sainte-Justine Hospital in Montréal under the supervision of Dr. Marie Lambert. The analyses of lead (from the blood sample) will be done at the *Laboratoire de toxicologie de l'Institut national de santé publique (INSPQ)* in Québec City under the supervision of Dr. Richard E. Tremblay. Your child's blood and/or saliva samples and your saliva samples will be kept in locked freezers reserved for the purposes of this study until the research objectives for their use have been accomplished, after which time they will be destroyed according to the usual protocol of the hospital or research centre involved. However, no sample can be retained for more than 25 years. After this period, all remaining samples will be destroyed.

During the 25 years, the biological samples may be used for other research projects related to the objectives of the health round or other objectives. These research projects may be conducted by researchers on the research team or researchers elsewhere.

If proposals for further analyses of the biological samples related to the objectives of this "health" round are submitted by research teams, such analyses can only be conducted after authorization by the Ethics Committee of the *ISQ* and the Research Ethics Committee of Sainte-Justine Hospital.

If requests for analyses other than those of the current "health" round have been approved by the Ethics Committee of the *ISQ* and the Research Ethics Committee of Sainte-Justine Hospital., your consent will again be required.

**12. Management of the Database**

The data from the "health" round will be entered into a database that may be cross-linked with groups of other data that you have provided or have agreed to provide in the general context of the QLSCD, always in coded form (namely, with no information that can reveal your individual identity). This database will be kept on the premises of each research team affiliated with this project and the *Institut de la statistique du Québec (ISQ)*. The computer systems will be secure, and cannot be accessed by third parties who are not part of this research project.

The database may be used for other research projects. Management of the databases will be under the responsibility of the *ISQ*. Each request for using the data of the "health" round must be made in writing to the *ISQ*. The researchers who will be authorized by the *ISQ* to use these data must have signed a confidentiality agreement before any data are made available to them. By signing this confidentiality form, the researchers make a commitment to respect the security and confidentiality regulations of *Direction Santé Québec* of the *ISQ* and its Ethics Committee. In all cases, without exception, no information revealing your identity or that of your child (name, address, telephone number, etc.) will be communicated to them.

Analyses of the data will be conducted by researchers currently affiliated with the study whose names appear in the list in point 2 in this form. The *ISQ* may also analyze these data and authorize other researchers to use these data following signature of a confidentiality agreement, strictly inside the secure premises of the *ISQ*. The complete list of researchers who have access to the data can be provided to you upon request.

The databases will be preserve as long as they can be used to advance knowledge and their security can be ensured

**13. Researchers' Responsibilities**

In case of unfavourable reactions resulting from the procedures required for this research, you and your child will receive all the care needed for your health, that is covered by the Québec hospitalization insurance and Medicare plans. By signing this consent form, you do not relinquish any of your rights under the law. Moreover, the *Institut de la statistique du Québec* and the study researchers retain their legal and professional responsibility towards you.

**14. Compensation**

A surprise gift will be given to your child by the nurse or research assistant at the end of the visit, and $40.00 will be given to you for your participation in the "health" round.

**15. Conflict of Interest**

There is no conflict of interest related to this research project on the part of the research clinicians or research centres.

**16. Participation is Voluntary**

Your participation is entirely voluntary. You are free to participate or not. Before giving us your answer, you can take all the time you need to think about your decision and discuss your participation with your family. Not participating in this particular "health" round or any of its parts does not prevent you from continuing to participate in other future rounds of the study. In addition, your child and you can withdraw at any time, without prejudice. If you withdraw from this round after the visit has been conducted, the biological samples and your data in the health round database will be automatically destroyed.

If you have refused to participate in the regular round of the 2008 data collection for the "I Am, I'll Be" study, but you have accepted to participate in the health round, you will again be asked to respond by telephone to the computerized questionnaire completed by the interviewer, usually administered in the regular round (duration approximately one hour). Information from the telephone interview can make a valuable contribution to the objectives of the health round. If you accept to respond to the computerized questionnaire, *BIP* will make arrangements with you to conduct the telephone interview.

## 17. If You Have Any Questions or Problems, Who Do You Call?

For any additional general information regarding this research project, please telephone the coordinator of the project at *Direction Santé Québec* of the *ISQ*, **Bertrand Perron** at **514-873-4749, ext. 6132, or toll-free** at **1-877-677-2087. For any question regarding the data collection or to notify us of a change of address, please call the coordinator at *BIP*, Véronique Dorison,** at **514-843-7304, or toll-free** at **1-877-843-7304**. A nurse will be available to answer any questions you may have at 514-843-7304 or toll-free at 1-877-843-7304. For any question related to the blood or saliva samples, you can call Dr. Marie Lambert at 514-345-4931 (ext. 5764).

For any information on the rights of your child as a participant in this research project, you can contact the legal advisor of the *ISQ* at 1-977-677-2087 (ext. 3304) or the *Commissaire local aux plaintes et à la qualité des services* (Complaints and Quality of Service Commissioner) of Sainte-Justine Hospital at 514-345-4749 or the Ombudsman of the Douglas Hospital at 514-761-6131 (ext. 3287) or the *Bureau de l'ombudsman* (Office of the Ombudsman) at the University of Montréal at 514-343-2100.

**18. Consent and Agreement**

I have carefully read this consent form for participating in the "health" round of the QLSCD. I have been given the opportunity and the time to ask any questions, and if I did they have been answered to my satisfaction.

Please indicate your choice:

**1.** I accept ☐ I refuse ☐ that measurements be conducted of my child's height, weight, waist, sitting height, blood pressure, and cardiac rhythm (heartbeat).

**2.** I accept ☐ I refuse ☐ that samples of saliva for the analysis of the salivary cortisol be provided by my child (in the week following the "health" visit).

**3.** I accept ☐ I refuse ☐ to provide samples of my own saliva for the analysis of the salivary cortisol (in the week following the "health" visit).

**4.** I accept ☐ I refuse ☐ that a blood sample be taken of my child and that the following analyses be conducted as indicated by my answering "Yes" or "No" to each (please circle "Yes" or "No" for each analysis):

4.1) risk of heart disease

YES NO

4.2) lead levels (I understand that if the level exceeds normal values, *Direction Santé Québec* will communicate with me and transmit the data to the *Direction de santé publique* (Public Health Department) in my region.

YES NO

4.3) genetic or biological factors related to behaviours

YES NO

**5.** I accept ☐ I refuse ☐ that the results of the tests be sent to me (cholesterol, triglycerides and blood sugar).

**6.** I accept ☐ I refuse ☐ that the sample(s) of saliva be provided in order to conduct analyses of genetic factors related to behaviours.

**7.** I accept ☐ I refuse ☐ that new laboratory analyses related to this study and authorized by the Ethics Committee of the *ISQ* and the Research Ethics Committee of Sainte-Justine Hospital can be conducted on the coded blood and/or saliva samples.

**8.** I understand that if new research to be conducted on the coded samples of blood and/or saliva related to other objectives has been approved by the managers of the bank of biological samples, the Ethics Committee of the *ISQ*, and the Research Ethics Committee of Sainte-Justine Hospital, I will be contacted to obtain my consent for this.

_____
Initials

**9.** I understand that the data collected as part of my participation in the "health" round may be sent to researchers who are not part of this agreement but whose research has been approved by the managers of the database and the Ethics Committee of the *ISQ*.

Consent of Parent or Legal Guardian

_____
Name of Parent or Legal Guardian (Please Print)

_____ _____
Signature Date

Consent of Participating Child

_____ _____ _____
Name of Child (Please Print) Signature of Participating Child Date

Consent of the child who understands but cannot sign Yes ☐ No ☐

Delegate of the Researcher (Nurse or Research Assistant)

_____ _____ _____
Name of the Person Who Obtained Consent (Please Print) Signature Date

**19. Researcher Commitment Form**

The research project and the procedures of participating in it must be described to the participant and/or his/her parent/guardian. A member of the research team must answer any questions the participants may have and explain that participation in the research project is free and voluntary. The members of the research team commit themselves to respect what has been agreed to in this consent form.

_____ _____ _____
Name of Principal Researcher (Please Print) Signature Date

The original of the this consent form will be kept at the *Direction Santé Québec* of the *ISQ* and a signed copy will be given to the participant

Space reserved for the nurse or research assistant present at the visit:

Samples taken: Blood…… ☐ Saliva (containing Oragene)……☐

*Please verify that the parent's consent indeed corresponds to what is indicated in the relevant section filled out on this form.*