

# **The Raine Study – physical activity levels, respiratory disease, and stress responsiveness in early adolescence**

## **Parent information sheet: adolescent genetic studies**

### **Purpose**

Your 13 year-old child is being invited to participate voluntarily in the above named research project. The purpose of this project is to study the genetic factors that are important in development of asthma, allergies, blood pressure variability, and sugar and fat metabolism in childhood. Therefore, your child is being asked to have a blood sample taken which will be used to try to identify the genes associated with immunoinflammatory conditions (asthma, allergies, increased propensity to infections and autoimmune diseases) and also genes associated with the metabolic syndrome (insulin resistance, high blood sugar, high blood cholesterol and triglycerides, high blood pressure, and obesity).

### **Procedures**

If you agree to participate, you will be giving your consent to the following:

1. Part of the blood sample taken for the Raine Study 13 year-old follow-up will be used for analyses of genes that may be related to asthma, allergies, blood pressure variability, and sugar and fat metabolism.
2. Your child's blood will be stored for approximately 40 years, since this is an ongoing study.
3. If additional blood is requested from my child in the future, the purpose of the additional sample(s) will be explained to me and I will be asked to sign another consent form to allow this.
4. If, at any time, you decide that you do not want your child's blood retained in storage for future examination you may contact the Principal Investigator or designated Raine Study staff and direct that you child's blood should be removed from storage. The sample(s) will then be destroyed.

### **Risks**

Risks associated with participating in this project are those associated with obtaining blood specimens. Drawing blood from inside the elbow may cause slight discomfort, bruising or swelling. In rare cases, there may be slight bleeding from the site, but this is unlikely if a band-aid is left in place.

Breaches in confidentiality concerning any of my personal information, including genetic results from genetic studies could cause me to feel upset or confused, or affect my relationships with other people. Confidentiality will be maximized by the methods described below.

### **Benefits**

There is no benefit to your child from his/her participation. Participation in this study may ultimately help doctors prevent or better treat respiratory illness, and/or blood pressure variability, and sugar and fat metabolism in childhood, by increasing their understanding of the causes of these illnesses and their long-term effects.

**Confidentiality**

All information collected will be kept confidential. Participants will be identified only by their study ID number. The Raine Study research assistants, principal investigator, and data entry personnel will have access to names of study participants.

The confidentiality of the results of the blood tests for genetic studies will be maintained by identifying all material with a code number. Only the necessary senior research specialists and research technicians will have access to this code. The only studies done on the blood will be related to development of asthma, allergies, blood pressure variability, and sugar and fat metabolism. No other use will be made of this material without first obtaining my written permission. This testing is being done for research purposes only and the usefulness of the information for individuals who are tested is not known. For this reason, my doctor and I will not be provided with the results of the genetic testing. The blood or results may be shared only with other academic and industrial researchers doing similar research, but my name will not be revealed. Studies will be undertaken in the laboratories of the investigators or their collaborators, located either in Perth (Professor Peter LeSouef, Professor Lawrie Beilin), nationally (eg Professor Len Harrison, Melbourne) or internationally (eg Professor Fernando Martinez, Tucson, USA). Any publication of the results will not include my name.

Even though the researchers will be careful not to tell you or anyone else the results of the genetic testing, there is a very small chance that results could accidentally become known to you or others. If this happens, and a result gets into the medical record that would make me a high insurance risk, it could lead to problems such as difficulty obtaining health insurance or employment discrimination, although this type of discrimination is illegal. The fact that these tests have no current clinical use makes it highly unlikely that these genetic studies will have such adverse effects.

**Participation costs and subject compensation**

There will be no costs for participation in the study and no compensation will be provided.

**Liability**

Side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. Necessary emergency medical care incurred as a direct result of the research will be provided without cost. You are free to refuse any part of the study and still remain in the study.

If you have questions concerning your rights as a research subject, you may call the King Edward Memorial and Princess Margaret Hospitals Ethics Committee office at (08) 9340 8221. Any complaints arising from your participation in this study should be directed toward the Executive Director of Medical services on (08) 9340 8222.

**Authorisation**

Before giving your consent by signing the accompanying consent form, the methods, inconveniences, risks, and benefits have been explained to you and your questions have been answered. You may ask questions at any time and are free to withdraw from the project at any time without interfering with routine care. Your participation in this project may be ended by the investigator for reasons that would be explained.

New information developed during the course of this study that may affect your willingness to continue in this research project will be provided as it becomes available. The consent form will be filed in an area designated by the King Edward Memorial and Princess Margaret Hospitals Ethics Committee with access restricted to Raine Study staff. You do not give up any of your legal rights by signing this form. A copy of the signed consent form will be given to you.