

## **The Raine Study Gen2: 28 year Vision and Vessels Follow-up Study**

### **Researchers Involved in this Study**

Professor Peter Eastwood, Professor Leon Straker, Winthrop Professor Daniel Green, Emeritus Professor Lawrie Beilin, Professor Trevor Mori, Associate Professor Philip Ainslie, Professor David Mackey, Associate Professor Stuart Macgregor, Associate Professor Alex Hewitt, Professor Christopher Hammond, Professor Elizabeth Milne, Professor Robyn Lucas, Doctor Fred Chen, Professor Mingguang He, Professor Jeremy Guggenheim and Professor Kathryn Rose.

### **Invitation**

We would like to invite you to participate in the Raine Study Gen2: 28 year Vision and Vessels Follow-up, a collaborative research project being led by Raine Study, Professor Daniel Green and his team from the School of Human Sciences (Exercise and Sports Science), University of Western Australia (UWA) and Professor David Mackey and his team from the Lions Eye Institute (LEI).

### **What is the study about?**

This study has three main aims. The first aim is to continue collecting the same core data as we did in previous follow-ups, so we can examine changes in your health and development over the years. The second aim is to assess artery function and health and to identify factors that are associated with impaired artery function. The third aim is to identify the genetic and environmental factors that are associated with eye health. The outcomes of this study will help us to understand factors that influence the health of blood vessels and eyes. The data might also allow us to better understand how the health of your blood vessels and the eyes might predict your future health.

### **What does participation involve?**

This follow up will require you to attend two separate appointments (details below) on two different occasions at venues you have attended before:

1. Vessel Health assessment at Raine Study House and the UWA Cardiovascular Research Laboratory in the School of Human Sciences (Exercise and Sports Science), Parkway, UWA (next door to each other).
2. Vision Health assessment at a separate appointment at Lions Eye Institute, 2 Verdun Street, Nedlands.

The assessments are explained below in more detail.

## A BRIEF OVERVIEW OF THE ASSESSMENTS

### Questionnaires

As part of the assessments we will ask you to complete some questionnaires for us. The links to a participant questionnaire will be emailed out to you for you to fill in online (30-60 mins). We will also ask you to complete a medical history questionnaire and for female participants a reproductive health questionnaire at the visit. If you do not wish to complete questionnaires online or do not have access to a computer we can either provide you with access to a computer or alternatively we can give you paper copies.

### Data Linkage

We would like to link the Raine Study dataset to publically held datasets. This would include educational outcomes held by Western Australia Department of Education and Training/School Curriculum and Standards Authority (state/national testing during primary and secondary school), Technical and Further Education and universities (after school education). This will allow research on factors that influence educational outcomes and in turn how education outcomes may influence other factors. We also wish to link to deaths registry, to update existing information on the Raine Study participants and their parents. This is important information to have before we contact you. We may seek to link to the midwives registry in relation to your offspring and also to hospital and primary care records to obtain reasons for hospital admissions. Other potentially available data sets managed by the Western Australia Data Linkage Unit for example mental health, health, child protection, disability, case registries (diabetes, cancer, autism) and medication use, all contain information that could be usefully linked with the Raine Study data. This type of data linkage can be an accurate and efficient way to enhance the data we have, decrease the burden on you (as we don't have to ask so many questions of you at follow-up) and allow comparison of the cohort with patterns in the population. All proposed projects will be assessed by the Raine Scientific Review Committee and obtain ethical approval.

### Visit 1 – Vessels Health Assessment

The first appointment will take place at the Raine Study House at UWA and at the School of Human Sciences, a short walk from Raine Study House. Parking will be provided. You will be asked to undergo non-invasive physical and vessel assessments, complete questionnaires and provide biological specimens. The assessment will last approximately **4-5 hours**.

### During the appointment at the Raine Study Vessels Assessment we will:

- Ask you to sign an informed consent form (based on the information provided to you in this information sheet).
- Ask you to complete a Medical History questionnaire.
- Measure your height and weight.
- Measure your waist, hip and arm girth with a tape measure.
- Measure your resting blood pressure using an inflatable cuff placed over your upper arm.
- Measure your whole body blood vessel function using a device called a SphygmoCor. The SphygmoCor also measures your carotid-femoral pulse (on your neck) wave velocity which is a measure of the elasticity of your arteries. This is a safe and non-invasive procedure.
- A fasting blood sample will be collected from your arm.
- Measure your brain blood vessel function (cerebrovascular function) while you do a number of "tasks". Blood flow to the brain will be measured using Doppler probes placed on each temple. This is a safe and non-invasive procedure.
- Measure your limb blood vessel function (peripheral vascular function). Blood vessels in the upper arm, thigh and neck will be scanned using ultrasound. This does not involve any radiation and is safe and non-invasive.
- Measure chambers of the heart for diameter and thickness using ultrasound (Echocardiogram) this is a safe and non-invasive procedure.
- Breakfast will then be provided for you.
- Conduct a whole body DEXA (Dual Energy X-ray Absorptiometry) scan which measures your body composition - lean mass, fat mass and bone mass and in females only we will also scan your breast to measure breast density.
- Females only do a breast scan (using a new non x-ray light based technology and complete a Reproductive Health (TiBs) questionnaire.)
- Conduct a physical fitness test (VO<sub>2</sub>max test). In this test your aerobic fitness will be measured while you are exercising on a treadmill or exercise bike while breathing through a mouthpiece.
- **DEBRIEF:** At the end of the examination your results will be discussed and you will be provided with a summary. If any of the results on the day or further results obtained after further analyses are out of the usual range or considered abnormal the Raine Study will contact you and arrange for you to see either your GP or a specialist. We will also arrange the Vision appointment for you at Lions Eye Institute.

Details of each of the tests involved in this visit are provided in the accompanying **Appendix 6 – Detailed information on study measures and tests.**

**For this appointment it is important that you:**

- **Fast overnight.** Please do not eat or drink anything (besides water) after 10pm the previous evening. On the day of your assessment do not eat breakfast, drink coffee or tea, smoke cigarettes, apply nicotine patches or chew nicotine gum (water is allowed). This is because certain tests require you to be fasted. We will have breakfast and snacks available for you after the brain and limb vessel tests. We also ask that you do not take recreational drugs in the 24 hours before the appointment.
- **Understand** that we will ask you twice (at the booking communication and consent process) about any medications you are taking or diagnosed medical conditions you have. Certain medical conditions such as heart conditions or being pregnant or medications such as blood pressure medications or vessel dilating drugs could make you ineligible to participate in some tests. We will not ask you to withhold taking any medications you need to take regularly however we will check what you are taking so there is no chance you will be adversely affected by doing the tests.
- **Wear loose clothing.** We ask that you wear loose clothing to the appointment which you feel comfortable laying down in and exercising in (including sports footwear and shorts). Some of the tests require exercising or lifting your top slightly, (e.g taking waist measurements) and lifting your short leg to obtain an ultrasound image of the artery in the thigh. The breast scan for females will require changing into a hospital gown.

## Visit 2 – Vision Health Assessment

The second visit will take place at the Lions Eye Institute (LEI) in Nedlands. Parking will be provided. We will ask you to do a number of different eye tests. The eye tests will be set up in a series of rooms at LEI; a Raine Study research assistant will greet you and direct you through the tests, along with the LEI staff. The tests will be done by ophthalmologists and other trained eye specialists. This visit will take approximately **2 hours**.

### During the appointment at the Raine Study Vision Assessment at LEI we will:

- Ask you to sign an informed consent form (based on the information provided to you in this information sheet).
- Assess sun exposure of the skin via a mole count on your arm and a skin impression taken from the back of your hand.
- Assess your eye health and functioning by a series of tests.
- **DEBRIEF:** At the end of the examination your results will be discussed and you will be provided with an eye report, and advised on results and whether you might need glasses (if you don't have them) or require a change of glasses.

Details of each of the tests involved in this visit are provided in the accompanying **Appendix 6 –Detailed information on study measures and tests**.

### For this appointment it is important that you:

- **Bring your glasses.** Please bring any prescription glasses that you have for this assessment along with a pair of sunglasses to wear after the session.
- **Understand** that for 1 to 2 hours after the tests your eyes will stay dilated, you might be sensitive to light and your vision might be slightly blurred. We suggest you do **NOT** drive till your vision has cleared.

## Voluntary Participation and Withdrawal from the Study

Participating in this study is voluntary. You can stop and withdraw from this study or any of the particular tests at any time, without giving an explanation. If you withdraw, you can choose what of the information you may already have given us at the appointment or in the online questionnaires we can keep. This will not influence our ongoing relationship with you.

## Privacy Statement

Your participation in this study and any information you provide will be treated in a strictly confidential manner. We will be matching your data from this follow-up with the information you previously provided as part of your involvement in the Raine Study. Our aim is to publish scientific articles based on the pool of responses we get from you and all other Raine Study participants. If we publish research papers from this follow-up, your data will not be identifiable.

All Raine Study data is stored in a separate, secure password protected database accessed only by Raine Study staff. The storage and management of the full data set will be handled by the Raine Study staff. University of Western Australia policies will be adhered to. Data is accessed, managed and stored according to the governance protocols outlined in the Raine Study Data and Biological Samples Access Policy – available on the Raine Study website ([www.rainestudy.org.au](http://www.rainestudy.org.au)). All identifiable data is retained in a secure location and is not permitted to come into the possession or control of any other organization or any individual unless required to do so by law. Only de-identified datasets (where we have removed identifying information) will be provided for scientific research, and then only for approved projects and approved investigators. Data can only be used to carry out the specific scientific research following approval by the Scientific Review Committee and with appropriate ethical approval. Only investigators approved by the Raine Study for a specific project can access the data for that specific project. Data is stored according to strict security and confidentiality protocols detailed in the Raine Study Access Protocol and in according to the legislation, codes and guidelines detailed in the Data Confidentiality Protocols. Research data will be securely stored for the recommended retention period as required by journal editors.

## Possible Benefits

You may personally benefit from your participation in this study because you will receive in-depth and up to date assessments on aspects of your health which are not usually available to the general public.

We will provide you with your results from the following tests, either on the day or a few weeks later:

- Results of your blood test, blood pressure and DXA (body composition) scan.
- Vessel results - artery stiffness score, fitness score and information regarding your artery health.
- Vision results - long and short sightedness score and amount of sun damage grade to the eye, and the health of the front and back of the eyes, including the blood vessels, nerves, and light-sensitive cells.
- Your participation in this study will also have a number of possible important benefits to the science community and to the greater community as a whole. By improving our understanding of vessel and vision health we can further understand and contribute to the science which leads to better prevention of diseases.

## Possible Risks and Risk Management Plan

When we communicate to book you in, we will ask you a few questions about your health and assess if you can do all the tests without problems. We will also check during the consent process for health conditions and details of any medications you may take. If during any of the tests you are not feeling well we can assist you. We will provide you with follow up information for your GP if needed.

There is a very low risk of the Raine Study being required by legally authorised agencies to provide collected information about yourself. Such data could relate to illegal or other activities. No such legal request has ever been made for Raine Study data. Some tests may cause some discomfort, but all effort will be made to ensure that the assessments are a pleasant experience and you can always stop the tests at any time. Please see **Appendix 6 – Detailed information on study measures and tests** for more information about the assessments and the possible risks.

## Raine Study Contact Details

If you would like discuss any aspect of this study please feel free to contact:

The Raine Study Gen2: 28 year Vision and Vessels Follow-up Coordinator, Diane Wood

Email: [rainestudy@uwa.edu.au](mailto:rainestudy@uwa.edu.au) or [diane.wood@uwa.edu.au](mailto:diane.wood@uwa.edu.au)

Ph: +61 8 6488 6952 or Mob: 0447 863 944

Sincerely,

Chief Investigator

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Approval to conduct this research has been provided by the University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics office at UWA on (08) 6488 4703 or by emailing to [humanethics@uwa.edu.au](mailto:humanethics@uwa.edu.au). All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.