



VIBeS

20YR FOLLOW-UP

Development from Birth to 20 Years



Dear VIBeS study participant,

This information booklet comes with a letter inviting you to take part in our 20-year follow-up (**VIBeS20**). It gives you important information about what is involved in this project. It also has details about who to contact if you have questions. This booklet is 8 pages long, so please ensure you have all the pages.

Before you decide to take part, it is important for you to understand why we would like to see you again at this time and what is involved. Please take the time to read this booklet carefully and discuss it with others if you wish.

It is your choice whether or not you take part in the research project. You do not have to agree if you do not want to. If you decide you do not want to take part, it will not affect any medical treatment and care you get in future.

If you would like to take part, we will ask you to sign a consent form for the VIBeS team to keep. We'll also provide you with a signed copy for you to keep. Please know that by signing the consent form, you are telling us that you understand what you have read in the booklet, you have had a chance to ask questions and are happy with the answers provided, and you consent to taking part in this project.

If you would like more information, please call us on **0434 062 900**. Alternatively, you can email us at **vibes@mcri.edu.au**. You will get the chance to ask questions when we call you in the next few weeks.

Thank you for taking the time to consider taking part in this next phase of VIBeS.

Best, VIBeS Team





What is VIBeS20 about?

The Victorian Infant Brain Study (VIBeS) is the world's largest ongoing study of brain development, thinking skills and behaviour of individuals born very preterm and full-term. This unique study, which has included a brain scan using magnetic resonance imaging (MRI) shortly after birth and in childhood (7 and 13 years of age) with developmental assessments at 2, 5, 7 and 13 years of age, has greatly improved our understanding of how individuals born very preterm develop and how this relates to their learning, memory and behaviour.

We are now inviting you to participate in a 20-year follow-up of the VIBeS study, which aims to look at development from birth to early adulthood, focusing on brain growth, thinking and learning, physical (motor, growth and cardiovascular function) and mental health (social functioning, mood and behaviour) outcomes. In this project, we are also interested in exploring other biological and genetic factors, such as examining the vessels in the brain that transport blood (cerebrovascular system) and specific genes, to see if they are associated with development.

This project will help us to understand how individuals develop from infancy to adulthood following very preterm birth.

Who is funding VIBeS20?

This project is being funded by the National Health and Medical Research Council and is taking place in Melbourne Australia by researchers and clinicians primarily at the Murdoch Children's Research Institute and Monash University.

Why am I invited to be in VIBeS20?

We are asking you to take part in this project because you were a participant in the Victorian Infant Brain Study (VIBeS).

What does taking part in VIBeS20 involve?

As part of this project, you will need to attend a study visit for one day at the Murdoch Children's Research Institute. We will ask you to complete different types of assessment and questionnaires at your appointment:

- A session looking at your thinking skills (problem solving, memory, attention, language, maths) will be performed by a research psychologist or provisional psychologist. An evaluation of your motor skills will be performed looking at you finger and hand coordination, as well as whole body movements. This session will take approximately 4 hours in total, but includes 2 breaks.
- We will also ask you to complete some online questionnaires about your physical and mental health. It is expected these questionnaires will take about an hour to complete and we will ask you to complete these questionnaires before you come in for your visit.

- Regarding physical health, we will measure your growth and body composition.

Optional parts of VIBeS20

The following parts of the project are optional. It is your decision whether you agree to these parts of the project. Whatever your decision, it will not affect participation in the rest of the project.

MRI scan

We would like you to have a brain MRI scan. This is a major focus of the current project and understanding brain structure and function at this age will be important to how the brain continues to develop into adulthood.

This scan will take place at the Children's MRI Centre at the Royal Children's Hospital. MRI is short for Magnetic Resonance Imaging. The MRI scanner uses a strong magnet to take clear pictures inside the body. Unlike an X-ray or CT scan, an MRI scan does not involve ionizing radiation, and is a safe, painless and non-invasive procedure.

The MRI Scanner is a large machine that is shaped like a tube and is open on both ends. It has a bed to lie on and a head rest. The bed moves into the magnetic cylinder so that the part of the body that is scanned is positioned in the centre of the machine.

Before the MRI, you will have the opportunity to practice the MRI procedure (called a "mock MRI"). This involves spending time with an experienced team member so that you can become familiar with the MRI scan procedure.

You will get to lie inside the “mock” MRI scanner that makes the same noises.

Some important things to remember:

- Since the MRI has a big magnet, care must be taken not to take any metal into the scanner room. Before your scan, we will ask you to complete an MRI safety questionnaire. On the day of the appointment, you will go through this questionnaire again with one of the MRI technicians.
- Before the scan, you will be asked to remove anything made of metal on your body (e.g., jewellery, hair pins, watches). You may also be asked to remove hair extensions or remove certain make-up as some of these items can interfere with MRI pictures.
- You will be asked to lie on a bed and we will make sure you are comfortable.

You will be given headphones because the scanner makes loud knocking noises while pictures are taken. You can watch a movie or listen to music.

Cardiovascular assessment

We would like to assess your heart health by looking at your blood pressure, heart rate and blood vessels. You will be asked to complete two cardiovascular tests:

- One while seated using cuffs on one arm and thigh, and a pressure sensor on the neck.
- A short ultrasound scan of your carotid artery using an external probe placed on the neck.

Accessing education linkage data

We would like your permission to let us link information contained about you in specific government databases. Being able to link data can be very useful for helping researchers understand health and development of individuals. It can also provide additional information on how individuals are faring. It also means that researchers do not always have to go directly to individuals for information.

This can save considerable time and energy. This additional information will help us understand your academic progress over time. We will collect information about you from the following databases or organisations:

- NAPLAN data from the Victorian Curriculum and Assessment Authority (VCAA)

Please know that this information will only be used at a group level and your information will not be used to compare you to another individual.



Genetic testing

Our bodies are made up of different types of cells. Inside each cell is the genetic material packaged as pairs of genes. You get one pair from your mother and one from your father. A gene is like a small microchip. It contains information and sends messages that help shape us. For example, genes can shape our eye colour and blood type. Each person has about 23,000 gene pairs. Genes are arranged along a chemical substance called DNA. Many health conditions or diseases are caused by a change in one or more genes. These conditions may emerge at birth or may appear later in life. However, sometimes a gene can change without causing a health condition.

Genetic research involves testing and studying genetic material, usually DNA. We are interested in understanding if certain genes can cause certain health and cognitive conditions. To do so, we want to take a sample of your saliva and test for several genes including some of the genes known to be important for memory and thinking. In particular, we will be testing for the apolipoprotein E (APOE) and Brain-derived Neurotrophic Factor (BDNF) genes, as well as certain gene features such as the length of telomeres (caps at the end of DNA strands), as these have been associated with development.



Are there any benefits for me and other people in the future?

We cannot guarantee that you will get any benefits from this project. However, we will give you a report of your evaluation. This report will outline your performance in the activities we administered that looked at your thinking and motor skills, and behaviour. Results will be provided in terms of performance ranges rather than actual scores. If necessary, we can speak to you to discuss the findings within the report and address any queries you may have. We will also send you a summary on the findings from your MRI brain scan. With your permission, we can send your reports to a medical professional or your family doctor (GP). We hope that this project will provide information that will improve our monitoring, care and treatment for individuals born very preterm in the future. We also hope this project will assist in identifying very preterm individuals at risk for difficulties and help to facilitate early intervention for these children.

Are there any risks or inconveniences for me?

Taking part in VIBeS20 should not cause you any harm. It is unlikely that you will become distressed by the assessments, however if this happens we will stop the assessment immediately. We do not expect any of the questions on the questionnaire to cause distress, but you do not have to answer any questions that you do not want to.

The main inconvenience is likely to be time taken for travel and the assessment. We will try our best to find the most convenient time, pay for your parking and offer a café voucher (\$10) during your visit. We will also offer a \$40 gift card voucher for your time. We can also help with travel costs for your visit if you have to travel a considerable distance (over 50km from the hospital). If it is difficult for you to travel to us, we can organise to complete the assessment through another method or location.

MRI

MRI scans are considered a safe procedure but some people can feel anxious during the scan. If you start to feel anxious, we will stop the scan.

We are taking the scans for research purposes. The scans are not meant to be used to help diagnose, treat or manage any medical condition. However, a radiologist will look at the images for unusual features. If the radiologist finds something that needs further examination or is unexpected, we will contact you and organise a referral to an appropriate medical doctor if needed.

The discovery of an unusual feature may help to get you the treatment needed. However, the discovery of an unusual feature could have consequences for you. It may affect your ability to work in certain professions or get insurance cover.

Please take time to consider the advantages and disadvantages of discovery of a health risk before deciding to take part in this aspect of the research project.

Genetic testing

We are doing genetic testing for research purposes. We will look at your genes for features relevant to the research project, however we will not be able to give you your genetic test results.

How will I find out the project results?

When the project is completed, a summary of the findings will be sent to you. Throughout the project, you will receive regular newsletters that highlight new findings and studies. Please let us know if you do not want to receive this information or the newsletters.

Can I withdraw from the project?

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If you leave the project we will use any information we have already collected unless you tell us not to. Whatever your decision, it will not affect any treatment or care you get, or your family's relationship with The Royal Children's Hospital.

How will you keep my information confidential?

Any information we collect from you will remain confidential and will not be included in your medical record. Only the researchers involved with this project and The Royal Children's Hospital Ethics Committee can have access to this information. We can disclose the information only with your permission, except as required by law. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access this information.

The study information will be re-identifiable. This means that we will remove your name and give your information a special code number. Only the research team can match your name to your code number, if it is necessary to do so. All study information will be stored securely in a locked filing cabinet in the Victorian Infant Brain Study (VIBeS) offices at The Murdoch Children's Research Institute. Your information and contact details will also be stored securely on a restricted access, password-protected computer database.

When we write or talk about the results of this project, we will report information about groups of participants only. This means that no one will be able to identify you.

We will keep your information until the youngest participant in this project turns 27 years old. The information will be kept indefinitely in secure storage after this time.

We may also need to share your study data with other ethically-approved research facilities, biobanks, or medical journals. If we need to do this, we will protect you by removing all identifying details from your data before we share it.

Thank you again for taking the time to read this information booklet. We hope you will take part in **VIBeS20** and help us improve the health and lives of future preterm babies.

CONTACT US

If you would like more information about the **VIBeS20** project, please call us
Telephone: **0434 062 900** or
Email: **vibes@mcri.edu.au**.

If you have any concerns and/or complaints about the study, the way it is being conducted or your rights as a research participant, and would like to speak to someone independent of the study, please contact the Director of Research Operations at the Royal Children's Hospital by phone on **03 9345 5044**.