

BIS Barwon
Infant
Study

PRIMARY SCHOOL REVIEW
Parent/Guardian Information and
Consent Booklet IN-CLINIC VISIT



Dear BIS Parents/Guardians,

You and your child are invited to take part in:

The Barwon Infant Study

PRIMARY SCHOOL REVIEW



This Participant Information and Consent Booklet tells you about this research project and all the steps and procedures specific to the BIS Primary School review. Knowing what is involved and why the BIS Primary School review is being conducted, will help you decide whether or not you and your child would like to participate in this research.

Please read this information carefully and note any questions that you wish to ask the BIS team. Before deciding whether or not to allow your child to take part you may also wish to talk about it with a relative, friend or your doctor.

Following this invitation, you will be contacted by the BIS team and given an opportunity to ask any questions about anything you don't understand or would like to know more about. If you and your child decide to participate, you will be taken through the consent process. You will be given a copy of this Information Statement and Consent Forms to keep.

Participation in this research is voluntary and we are very flexible with participation. If you do not wish for you or your child to participate, you do not have to. You can choose not to participate at this time point and remain in the BIS study. You can withdraw your child from the project at any time without explanation and this will not affect their access to the best available treatment options and care at Barwon Health or any other health providers.

If you would like more information, please call the BIS Study mobile on 0400 432 976, or email us at bis@barwonhealth.org.au

There will be further opportunity to ask any questions that you may have when we call you in the coming weeks, and on the assessment day/s.

Thank you for taking the time to consider being a part of the next phase of BIS. All this information is also available on our website at www.barwoninfantstudy.org.au

The Barwon Infant Study

PRIMARY SCHOOL REVIEW

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1. What is the purpose of the BIS Primary School Review?

We have gathered a wealth of information about your child's early life environment. At the BIS Primary School review we will be aiming to understand how these early life factors relate to health of school aged children. By school age, we may start to see previous health issues resolve and different challenges arise. Generally, food allergy becomes less common, but mental health issues related to the modern child's lifestyle (e.g. internet and device use) may start to emerge.

We are interested to learn about how your child's environment and lifestyle links to their physical and mental health. The main areas of focus include neurodevelopment, mental health, cardiovascular, dental and respiratory health. We will continue to collect information on your child's physical activity and diet, as well as important information about you, your family and home environment.

In addition, we would like to build on the data and samples collected during pregnancy to investigate the determinants of maternal health. In particular, we would like to investigate how a mother's genetics, environment, diet and lifestyle influence the composition and function of her gut bacteria, blood fats and other biological markers relate to her cardiometabolic and psychological wellbeing.

Data collected at this review will be used for many years to come and will support a wide range of research, including investigation of how our modern environment, lifestyles, and genetics interact to cause and influence the development of illness and disease.

The Barwon Infant Study (BIS) is an ongoing collaborative research project conducted by researchers from Barwon Health, the Murdoch Children's Research Institute and Deakin University. The project aims to improve the health of children by understanding factors that influence the health and development of babies and children. We hope to use knowledge generated from BIS to help explain how our modern lifestyles, the environment and genetics interact to influence or cause the development of illness and disease, and to find new ways to help prevent them. BIS is primarily funded by the National Health and Medical Research Council of Australia.

The BIS Primary School review has received additional support from the Gandel Trust, Eirene Lucas Foundation and Gwyneth Raymond Trust with help from the Barwon Foundation.



2. What does participation in this research involve?

We will invite you and your child to attend an in-clinic appointment, either at the Child Health Research Unit, Barwon Health or remotely. The BIS team will always endeavour to accommodate an appointment time and day that is most convenient to you and your family.

The components of the review that you and your child will be invited to participate in includes:

Initial telephone call (5-10 minutes)

We will call you to discuss the Primary School review and answer any questions that you may have (5-10 mins). During this call we will go through consent and check if there is anything you would like the research team to know about your child to consider during the school review. The BIS team will be making sure your child is comfortable and having fun throughout the review.

In-clinic appointment (approx. 4-5 hours).

To minimise the burden on parents, the review has been designed to be appropriate for your child to participate without a parent/guardian present for most measures. We require a parent/guardian to attend for approx. 30 mins at the beginning and end of the appointment. This is to complete the consent process, answer questions and support your child. Parents/guardians are most welcome to stay for the entire appointment and if you do leave we ask that you stay close by.

- > As outlined in this booklet on pages 4-7, we will invite your child to participate in a range of cardiometabolic, anthropometric, neurodevelopment, respiratory and dental measures, and an optional blood test. The children will also be offered skin prick allergy testing. This will take approximately 4-5 hours, including appropriate snacks/rest breaks.
- > At this appointment we will also invite BIS mothers to complete a series of non-invasive measures, as outlined in this booklet on pages 8-9. These measures will take approximately 30 minutes.
- > Online questionnaires for parents to complete (30-45 minutes).

- > Your child will be asked to wear an accelerometer "belt" (physical activity monitor) for 1 week.
- > Parking vouchers will be made available so that you can easily attend your appointment at the Child Health Research Unit, Barwon Health. We will also help with your travel costs to attend this appointment by giving you a \$20 pre-paid gift card.

TO NOTE: The research team will ensure that the in-clinic visit is an enjoyable and interactive experience for the participating children. We will check before starting each activity that you and your child are happy to go ahead. Even if you provide consent, you or your child can still opt out of any activity at anytime.

BIS MOTHERS



We would like BIS Mothers' to take part in an in-clinic assessment with their child, whether they are in good health or have health problems. These straight-forward measures will be very helpful for BIS and provide greater insight into the development of BIS children. We would also like to complete height and weight measurements on BIS Fathers that are happy to participate. This does not require BIS Father's to attend.

YOUR CHILD'S TEACHER



With your permission, we will send your child's main school teacher questionnaires asking about your child's academic performance and classroom behaviour.

With your permission, we may video record the assessments for safety and quality purposes. All media will be securely stored to ensure your child's confidentiality. You may of course request that the review is not recorded on video.

THE PRIMARY SCHOOL REVIEW IN-CLINIC APPOINTMENT

The in-clinic appointment will involve a series of measures and activities conducted at either the Child Health Research Unit, or remotely. We estimate that it will take approx. 4-5 hours for your child to complete all measures with appropriate breaks/snacks. This will also allow us to conduct some brief maternal measures both at the beginning and end of the appointment.



BIS offices



Via email

OVERVIEW

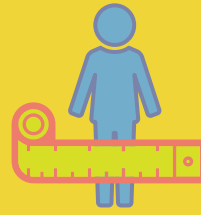
Growth		
Lung health		
Heart Health		
Brain Health		
Eye Health		
Dental Health		
Biological Samples		
Fitness		
Allergy Test (optional)		
Blood test (optional)		
Questionnaires		

From your child



Lung health

- > Lung function is measured by blowing into a mouthpiece called a spirometer. This device measures the volume of air moving in and out of the lungs. The second test is called the Forced Oscillation Test (FOT) and will measure the mechanics of your child's airways using air waves (wobbles). Your child will sit and breathe into the mouthpiece for 16 second measurements.
- > The third test is called Multiple Breath Washout (MBW) and will record how long it takes your child to breathe out nitrogen, naturally found in our lungs. It is the same test your child completed as a baby and at the BIS Preschool review. Your child will be given 100% oxygen and be sitting up comfortably breathing into a mouthpiece. We will put on a fun kids show for your child to watch. The test will be repeated so that we have enough data for analysis. Your child will be given a rest between each measurement.
- > Your child will then receive the blue puffer Ventolin (safe, over-the-counter, medication) via a spacer device, to see if this increases their lung function. Your child will have a 10 min break and then repeat the spirometry and FOT measures.



Growth

- > We will measure your child's growth, such as height, weight, circumferences and skin fold thickness in a private setting fully clothed. We will also conduct an eczema assessment.
- > We will assess your child's bone quality using an ultrasound measurement of the heel. During this procedure your child will be required to place one foot in the ultrasound machine for a few minutes. This will measure how quickly the ultrasound wave passes through your child's heel and how much of the ultrasound wave is absorbed. The ultrasound measurement is a rapid, painless procedure and does not involve x-rays.



Allergies

- > As part of your visit, you will be offered the opportunity for your child to have skin prick test to assess allergic sensitisation. This is the same test your child may have had at the 12 month and/or Preschool BIS reviews. We will provide you with your child's result on the day of testing. We will also provide referrals and results to your nominated doctor (if required).



Heart health

- > BIS is the only study in the world to have repeated cardiovascular measurements from 4-6 weeks of age into childhood. We hope that the findings will help us investigate changes in arteries of children as they get older and start preventing cardiovascular disease much earlier in life.
- > As completed in previous BIS reviews, we will perform an ultrasound on your child's neck and abdomen. This measures the thickness of the arterial blood vessel wall. Your child will be watching a fun TV program during the entire assessment.
- > An electrocardiogram (ECG) tracing will be completed using a chest monitor. This will help understand how the autonomic nervous system, responsible for heart rate and breathing, could contribute to child health problems, such as child anxiety and heart rate.
- > Blood pressure measurements will be completed on one arm and one leg. The device also provides measures on blood vessel function and movement.



Brain health

- > Your child will be invited to undergo a neurodevelopmental assessment. The assessment will take about an hour and will be completed in a room without distractions, with a psychology research assistant under close supervision from a psychologist. This is an interactive assessment involving a series of games/tasks, assessing language, social and emotional skills, problem solving and memory. They will also be asked to complete a short questionnaire asking about their general health and wellbeing. To help BIS understand how children focus their attention, your child will also be asked to wear special glasses for 5-10mins that track eye movements to see how your child is interacting with these games/tasks.
- > After the appointment, we will provide you with a short written report on your child's neurodevelopment. If there are any concerns about your child's language or thinking, we can help provide you, your child and your nominated family doctor with referral for further assessment if you chose.



Dental health

- > Bacteria in the mouth cause tooth decay, which is the most common childhood disease, affecting almost half of Australian children. Bacteria also contribute to cardiovascular disease, which affects half of the adult Australian population. Interestingly, healthy teeth have been linked with healthy hearts and it is emerging that oral and heart health are tightly linked. In studying the relationship between bacteria and oral and heart health in children, we hope to discover ways to detect and ultimately prevent diseases of the mouth and heart. This is why we are asking for samples of saliva and dental plaque from your child.
- > A registered oral health professional will examine your children's mouth and teeth, checking for cavities/dental decay as well as any developmental marks on the teeth. In addition, we may take a 3D scan of your child's teeth to document our findings. The 3D scan will be only of the mouth and your child will not be identifiable in these photos. The 3D image may be used to improve data collection and software analysis of future scans. The assessment is very well tolerated and take 10-15 mins to complete. You and your nominated health professional will receive a report following your child's dental examination including a 3D image of your child's teeth. You will also have access the BIS non-urgent dental advice via the BIS email or phone.



Biological samples

The biological samples are a key strength of BIS. The samples will be stored and used for a wide range of tests. With your permission, we would like to collect the following samples.

Prior to your visit, we will provide collection kits for urine and stool samples. We will also collect a sample of your child's saliva and non-invasive swabs including a cheek (buccal swab), dental plaque and nose swab.

We will offer an optional blood test. The blood test gives us lots of useful information and is done by an experienced technician, who are skilled at reducing discomfort or worry. We will offer the use of an anaesthetic (numbing) cream prior to the blood test. Children usually tolerate the blood test very well, especially with the anaesthetic skin cream.

Tooth Fairy: We would also like to collect at least one of your child's 'baby teeth' after they fall out. Teeth can be used to measure exposure from before birth, infancy and early childhood. We will provide collection kits via mail and certificate of appreciation with a small remuneration.



Fitness

At the review, we will do 3 fun physical assessments to measure muscle function and cardiovascular fitness.

- > **'Jumping Beans'** we ask your child to see how far they can jump horizontally using both legs from a standing position.
- > **'Mighty Muscles'** we will ask your child to grip and squeeze a dynamometer as hard as possible.
- > **'Step Up'** we will ask your child to complete a step test for 3 mins. Once the 3 minutes is completed your child is asked to sit in a chair and heart rate is assessed for 1 minute.
- > **Activity Belt** As per the BIS Preschool Review, we will provide your child with an accelerometer to wear. The small physical activity monitor is attached to an elastic belt and worn on your child's right hip (under or over clothes). We hope that your child will wear this for seven full days to help us track their physical activity. We will provide you will postage bags to mail the accelerometer (activity belt) back to us.



Eye health

Early life is a sensitive period for the development of the eye and there is little understanding of which early life experiences impact eye health.

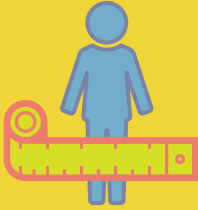
As part of your visit, we will ask your child to complete a series of eye and vision assessments. This will take 15-20 minutes in total and will be completed by a trained researcher. In a room with normal lighting we will ask your child to sit comfortably on a chair and read the smallest line that they can see on a standard letter chart. We will also check your child's depth perception by asking them to look through a lens and tell us what they see. Then we will ask your child to place their chin on a chin rest to look into devices that can measure the size of the eye and how light travels within the eye. The room will then be dimmed to allow us to image the back of your child's eye, which requires them to sit on a chair, rest their chin on a chin rest and look at a fixation target. We will take images of the back of both eyes (the retina) to examine blood vessels and other anatomy such as nerves.

There are no eye drops or touching of the eye involved in any of these assessments. This eye and vision assessment is not a substitute for a comprehensive eye health exam. We will provide you and your child with a referral if your child is unable to meet all of the criteria for this assessment.

From BIS mothers



At the follow-up visit to the BIS offices, mothers will be invited to participate in:



Body & Bone health

- > Measurement of height and weight (full clothed and in a private setting). These measurements will take approx. 5 minutes.



Heart health

- > We then measure your blood pressure using a computer program that also measures your heart rate and pulse wave analysis. This will give BIS information about your blood vessel function. These cardiovascular measures will take 5-10mins. The BIS team member will discuss with you if there are any results outside of normal range. If so, results will be sent to your nominated doctor.



Brain health

- > A short language assessment on an iPad. This will take approx. 5 minutes.



Biological samples

- > We would like to collect new biological samples from you. This will allow the BIS team to compare measures you provided from the time you were pregnant.
- > We will provide urine and stool collection kits prior to your appointment and ask you bring these samples to your appointment.
- > If you agree, we would also like to collect a small blood sample from you.
- > We can offer you numbing cream and the test will be completed by an experienced phlebotomist, nurse or doctor who are skilled at reducing any discomfort or worry that can surround these tests.
- > We may also be able to assist with the collection of doctor requested bloods. Please check with a BIS team member prior to your appointment.



3. Does my child have to take part in this research project?

Participation in any research project is voluntary. If you do not want your child to take part in this review, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

All components of this review are optional, you can agree to none, some or all of the components for yourself and your child. The more children that take part, the more valuable the resource becomes. We understand that families are busy and we are grateful for everything your family has and may be able to contribute to BIS.

4. What are the alternatives to participation?

It is up to you to decide if your child takes part in the BIS Primary School review. Your decision to participate in the Primary School review will have no bearing on clinical care your child receives from Barwon Health. If you do not take part in this review, we would still like you and your child to still remain in BIS as your child grows older.

If you would like to discuss how you and your family can best contribute to the study, please contact the BIS team on **0400 432 976**.

Even if you and your family are no longer living in the Barwon region, you are still able to continue being a part of the BIS study. A BIS team member can discuss with you the different ways of being involved in this project.



5. What are the possible benefits of taking part?

The information we gain from this study is likely to help develop strategies that may reduce the risk of disease among children and adults in Australia and around the world. However, we cannot guarantee or promise that your child will receive any direct benefits from this research. It is also possible that the data and biological samples will be used to develop specific preventative and/or treatment agents and technologies that may benefit Australian or international businesses.

We will be able to provide you with the following regarding your child's development and health:

- > Growth and body composition from infancy forwards.
- > Eczema assessment.
- > Blood pressure.
- > Lung function.
- > Dental health
- > The presence of allergic sensitisation to specific pollens, animals and foods.
- > Cognitive and physical skills.
- > Access to the BIS non-urgent dental email advice line.

We will provide BIS mothers with information regarding:

- > Their weight and body composition.
- > Blood pressure.

If clinically-significant abnormalities are detected as a result of the BIS testing, you will be informed and you will be provided with a follow-up letter for your nominated doctor, specialist or health professional.

There is no cost involved in continuing to be a BIS participant. Parking vouchers will be made available so that you can easily attend your appointment at the Child Health Research Unit, Barwon Health. We will also help with your travel costs by giving you a \$20 pre-paid gift card before you leave.



6. Are there any inconveniences or risks of taking part?

Taking part in the BIS Primary School review should not cause you or your child any harm. All the assessments are safe for children. We will check before starting each activity that you and your child are happy to go ahead. The main inconvenience for you is likely to be the time it takes to participate. The estimated times for each component are listed above.

‘Lung Health’ assessments: Your child may experience a slightly dry throat during or shortly after the lung function test. If this happens, we will offer them a glass of water. The administration of salbutamol, and asthma drug, is generally very well tolerated but can be associated with an elevated heart rate and nausea.

‘Heart Health’ assessments: There are no major risks associated with these tests. We will use an inflatable cuff on your child’s arm and leg to measure blood pressure and to measure stiffness of their blood vessels. It may be slightly uncomfortable for a short time while the cuff inflates.

Dental assessments: There are no risks associated with dental examinations and it is non-invasive. If any dental disease is detected, we will give you a letter to take to a dental practitioner of your choice to seek further advice. We are unable to provide any treatment or cover any associated costs beyond screening.

Blood sample: There are no major risks associated with a blood test. Our staff are trained in taking blood from infants and your children. We will offer the use of an anaesthetic (numbing) cream on

your child’s skin over the site where the blood is to be collected. Children usually tolerate the blood test very well, especially with the anaesthetic skin cream. However, they may feel some discomfort, even though our staff are trained to reduce this risk. It can also leave a small bruise.

Skin Prick Testing: The skin prick testing will be done on your child’s back by a trained BIS team member. It is generally well tolerated, but can cause a minor degree of discomfort and itchiness. The risk that your child will have a generalised allergic reaction to skin prick testing is less than 1 in 1000. If this were to occur, the paediatric doctor on call for the Geelong Hospital will be notified and medications administered if required.

Trained clinical staff will be responsible for monitoring your child during each of these tests and/or procedures. If any side effects occur, the BIS paediatric doctor, or the paediatric doctor on call for the Geelong Hospital, will immediately be notified, and treatment will be administered as soon as possible if it is required. In the unlikely event that you or your child are hurt, or feel unwell as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you. We do not anticipate any psychological risks or effects as a consequence of participation in the study. However, if you or your child becomes upset or distressed as a result of participation in the review we will be able to arrange for any appropriate support. Any counselling or support will be provided by qualified personnel who are not members of the research project team. This support will be provided free of charge.

7. What if we withdraw from this research project?

You are free to withdraw you and your child from participation at any time, without giving a reason.

You are also free to request that data and/or biological specimens collected from you or your child up until the point of withdrawal be removed from BIS and discarded.

We will not be able to remove data that has already been included in published studies or report. Unless specifically directed not to do so, we will retain data and biological specimens to include in the analysis of this research project and/ or other future ethically approved research projects.

8. What happens when the research project ends?

The Barwon Infant Study (BIS) is an ongoing research project. Information collected as part BIS will be analysed and reports of the findings will be prepared periodically. The results may also be published in medical journals. We will send you a letter summarising the study's main findings to date after the final Primary School review has been completed.

At the end of your child's Primary School review we would like to invite you to continue to participate in the BIS. The longer we follow the children and families, who have participated in BIS, the more we can learn about how to give children a healthy start to life. We will send you more information as the study progresses.

Each family
in BIS is
irreplaceable.

It is crucial that we keep in touch with as many participants as possible, even if you have been unable to participate in previous reviews. **If you have changed your name, address, telephone number or email please contact us.** Thank you.

Call/text: 0400 432 976

Email: bis@barwonhealth.org.au

Website: www.barwoninfantstudy.org.au

Follow us on Facebook:

<https://www.facebook.com/barwoninfantstudy/>

9. What will happen to information collected about me and my child?

By signing the consent form, you consent to research staff collecting and using personal information about you and your child for the research project. Any information obtained in connection with this research project that identifies you or your child will remain confidential. Data will be stored in a password protected computer file or in a locked filing cabinet in a lockable office at the Child Health Research Unit.

The information collected about your child will be used in publications in medical or scientific journals. You or your child will not be referred to by name in any study, report or publication. Your identities will remain confidential. Medical and health related information about you and your child will be collected by trained research staff who will employ strict procedures to ensure that these details remain confidential and are not forwarded to any third parties. Any data extracted from medical records will be de-identified prior to analysis and incorporation in any publications.

Confidentiality is extremely important to the BIS research team. For this reason, the only people who will have access to identifiable information will be BIS personnel, the study doctor, as well as BIS Steering Committee for monitoring safety and quality of the project. The confidentiality of you and your child's medical and other health related information collected during the BIS will be maintained to the extent permitted by applicable laws.



10. What will happen to my and my child's biological samples?

BIS biological samples

Biological samples are important for showing how people's body systems adapt to their life journey. The samples provide information about genetic makeup (like DNA) and environment (like exposures to every day pollutants), and how these might contribute to health and disease. The samples may also show how the micro-organisms we all have in our bodies can influence our health- for better or worse. It is also possible that samples will be used to develop specific preventive and or treatment agents. The goal is to improve health outcomes and develop new treatments.

You and your child have previously provided biological samples as part of your participation with BIS, for the following research purposes;

- > Urine samples stored for the measurements such as of modern chemicals, plastic derivatives, bio-chemicals, metabolites.
- > Stool samples stored for the measurements such as of the microbial composition and metabolic products present in the child's gut.
- > Nasal swabs, buccal swabs and saliva stored for measurements such as the microbial composition of the child's mouth and nose, isolation of DNA and measurements of inflammation.
- > Hair samples stored for measurements such as possible exposure to man-made products/chemicals present in the household environment.
- > Blood and tissue samples stored and used for measurements such as isolation and storage of various components of the blood and tissue cells (e.g. plasma and immune cells) and functioning.
- > Breast milk stored for measurements such as breast milk composition and microbial profile.

BIS Primary School review samples

As part of the BIS Primary School review we would like to collect new types of biological samples including;

- > A baby tooth stored for measurements such as environmental exposures from pregnancy, infancy and early childhood.
- > Dental plaque swabs stored for measurements such as the microbial composition of the child's mouth, inflammation and mineralisation.

Genetic material

Every person has about 23,000 genes. These are passed down in families from parents to children; you get half of your genes from your mother and half from your father. Our genes contain the information that makes us who we are, including eye colour, blood type, height and whether we are born a girl or boy. Some health conditions are caused by a change in just one or more genes. However, most of today's common diseases are influenced by small differences in or near many genes, as well as the environments that we live in. Our environment can alter gene expression, that is, how a gene functions. Studying genetic material like DNA helps researchers understand how traits and disease are inherited (passed from parents to children) and expressed (an individual having or not having a specific characteristic). This in future might tell us how genes are turned on and off and how they affect disease outcomes.

The genetic tests we are doing are for research purposes only. We will be looking at genes at the population level. We will not give you the results of any genetic tests. This is because at this stage, we do not know what the results mean and they would not change the way we, or others, care for you or your child.

11. Where will the biological samples be stored?

All samples will be stored in the BIS study freezers at Barwon Health until further analysis. To protect your child's identity, all of their samples will be labelled with a study identifier number only, with no personal details.

Only the members of the research team and BIS collaborators will be able to access these samples and will update reports on their location and processing. The freezers are locked and can only be opened by members of the research team who have access to the key. Some of the biological samples collected may be analysed at collaborating laboratories or services in Australia and/or overseas, as some analyses can be done in only a few places worldwide.

12. How long will the biological samples be stored for?

Over time, researchers will analyse the data and samples in many different ways to answer new and diverse questions to human health- therefore, the value of you and your child's information will keep growing the long after this assessment. Analysis can only happen under strict guidelines for access and confidentiality, as funding becomes available.

For participants in this project that are under 18 years old, the data and biological specimens collected will be kept at least until the youngest participant turns 25 years old. The purpose of storing you and your child's data and biological specimens is to answer questions in the future, so we expect to keep data and biological specimens for a long time.

Future use of biological samples and data

With your consent, we would like to store the biological samples for an indefinite period. On the consent form we ask you to consider giving consent to keep any remaining samples for other future studies relating to the health and development of children. As such, if you give consent to the storage and use of biological samples collected for future ethically approved research conducted by BIS researchers and collaborators in Australia and overseas, then these samples will be securely stored in the BIS Biobank and Cohort database for an indefinite period. We won't come back to you for your consent, because science evolves quickly and it is not possible to predict what these additional future studies will be.

Any researcher(s) wishing to access data and/ or specimens in the future must complete a comprehensive application detailing the proposed research team, purpose and design of the study, and any ethical considerations. This application will then be reviewed by the BIS Steering Committee and approved by the Barwon Health Human Research Ethics Committee.

We may also merge data with other studies for questions that can only be answered with very large numbers of participants (for example, investigating rare health conditions). This means that your samples and digital data can be used for full benefit, even when analysis is very expensive, very specialized or very labour intensive. The samples or data will only ever be identified by a code number, not a name. Note that data or samples sent to other countries for ethically approved research may not be covered by Australia regulations.

13. Who has reviewed the research project?

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate. The ethical aspects of this research project have been approved by the Barwon Health Human Research Ethics Committee.

This project has also been reviewed by the Department of Education and Training and permission has been granted to the Barwon Infant Study to conduct research in Victorian early childhood settings.

If you have any concerns about the project, or the way it is being conducted, and would like to speak to someone independent of the project please contact the Barwon Health Research Ethics Office on **03 4215 3372**.



The BIS Consumer Reference Group

Participant experience is very important to the BIS team. Your feedback and suggestions are crucial. We would like to float our ideas and get your opinion.

We are open to whichever way you prefer to provide feedback - such as web-based discussion groups, email, text or phone. We would be grateful for any level of contribution, so there is no minimum commitment required. If you are interested in helping out the BIS team by having your say, or for more details, please contact:

Nakita Clements, Project Coordinator
Email: BIS@BarwonHealth.org.au

FURTHER INFORMATION AND WHO TO CONTACT

If you would like more information about the project, or if you need to speak to a member of the research team please contact **0400 432 976** or **0400 071 218**.

