



# BIS Medicare & PBS Data Linkage

Barwon Infant Study

EMAIL  
bis@barwonhealth.org.au

MOBILE  
0400 432 976

WEBSITE  
barwoninfantstudy.org.au

## Dear BIS Parents/ Guardians

We had a great start to 2020, as the BIS research team set off to local primary schools on the BIS bus. The BIS Primary School review ran smoothly at the schools and worked well for the families participating, plus the BIS kids had a great time too.

In the context of COVID-19, we have had to postpone our BIS Primary School visits for now. However, there is still a lot of important work BIS can do.

By school age, we know children may face different health challenges compared to early childhood. As part of our research, we are interested in understanding how BIS children access health care services and what treatments they receive. To help us with this, **we will be seeking your permission to access you and/or your child's Medicare Benefits Scheme (MBS), Pharmaceutical Benefits Scheme (PBS) and/or Australian Immunisation Register (AIR) data.** This is a health research practice called 'data linkage' which you are likely familiar with from our recent Victorian State Data Linkage project. On this occasion however, we are interested in **Commonwealth Government Data Linkage.**

Data linkage will allow us to address multiple important health questions without adding burden to you as a BIS participant. By linking these records the study can obtain very accurate and useful health information, without asking you to recall specific dates and details about health-care services. The period of your child's data we would like to access is from when they were born until they turn 14 years of age. You will also be asked if you are happy to provide consent for the study to access this data up until your child turns 18 years old.

This booklet contains further information on the research project. We will send you the optional **BIS Services Australia and Australian Institute of Health and Welfare Data Linkage separate consent forms** and call you to discuss any questions you may have.

Thank you again for your time and commitment to improving the health of our community.

With best wishes,

**Pete Vuillermin**, Professor of Paediatrics  
Deakin University | Barwon Health

**Anne-Louise Ponsonby**, Professor of Epidemiology  
The Florey Institute | University of Melbourne

### 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.

Please contact the BIS team or just hit REPLY with new address or updated details.

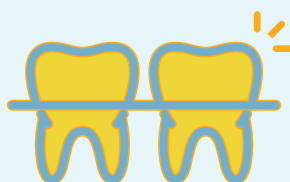
Call/text: **0400 432 976**

Email: [bis@barwonhealth.org.au](mailto:bis@barwonhealth.org.au)

Website: [www.barwoninfantstudy.org.au](http://www.barwoninfantstudy.org.au)

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# What is Data Linkage, and why is it important?

Data Linkage is a process that allows studies to access their participants' administrative data. Administrative data is routinely generated on everybody, for example, when you visit a hospital, fill a prescription, get married, have a child or when your child enrolls in school. Data linkage is a widely used strategy in medical research and has played a crucial role in many public health discoveries. Performing data linkage will help us to address numerous important research questions without placing an added burden on you as a participating BIS family.

## Participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

## Withdrawing from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw you or your child from the study at any time by completing and signing the 'Parent/Guardian Withdrawal of Consent Form'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw you or your child from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you or your child. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you and your child.

## What is a data custodian?

Data custodians are the people who hold the 'keys' to the administrative data. They store personal information (eg.name, address, date of birth) and also content information (eg.health information such as diagnosis and treatment details). Data custodians have a responsibility to protect the confidentiality of administrative data.

## What is a data linkage unit?

Data linkage can be complicated! Therefore, data linkage units have been established within state and federal departments to liaise between researchers and data custodians. The linkage units are able to gather data from multiple custodians and link it with a list of research participants provided. This is a secure way for researchers and state and federal departments to work together.

# How will my data be linked?

1. If you decide to provide your consent, we will provide the information required to complete accurate data linkage (e.g. name, date of birth, address, gender) to the data custodian or linkage unit (such as the Australian Institute of Health and Welfare, Services Australia or the Centre for Victorian Data Linkage).
2. The data custodian or government linkage unit will then use the information we provide to link with information held in their database.
3. The data custodian or government linkage unit then replaces identifying data with a unique identifier, thus enabling them to provide the BIS team with de-identified linked data.

For example, we can obtain detailed and accurate information on the timing, dose and type of antibiotic prescriptions from the Pharmaceutical Benefits Scheme (PBS). This is very important to our research regarding gut bacteria.

In previous BIS questionnaires we asked questions such as:

**"Has your child been given any antibiotics in the last 12 months?"**

**"How many courses of antibiotics has your child received in the last 12 months?"**

**"For what reason did your child receive antibiotics?"**

This level of detail is difficult for parents to recall accurately. By linking with the PBS database we can obtain highly accurate and detailed information to use in our analyses. Accuracy and detail are crucial to providing meaningful answers to important research questions.

NAME	DOB	SEX
Johnny SMITH	01/01/2011	M

DRUG NAME	DIAGNOSIS	ITEM CODE	MEDICINE CODE	FORM STRENGTH	TOTAL SCRIPTS	DATE OF SERVICE
Amoxicillin	Tonsillitis	49H	1887h	250mg	1	23/4/2017

For example, from a data request we will receive information that looks similar to this: The green section containing your identifiable information is then removed and replaced with your unique BIS ID, shown in orange. This is then how the BIS researchers will receive the data.

BIS ID	DRUG NAME	DIAGNOSIS	ITEM CODE	MEDICINE CODE	FORM STRENGTH	TOTAL SCRIPTS	DATE OF SERVICE
C1234	Amoxicillin	Tonsillitis	49H	1887h	250mg	1	23/4/2017



# Which records are BIS interested in?

## Your child's records

You will be asked to sign a consent form authorising the study to access your child's complete Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) and/or Australian Immunisation Register (AIR) data as outlined in the consent form.

Medicare collects information on your child's doctor visits, while the PBS collects information on the prescription medications you and your child have filled at pharmacies. The Australian Immunisation Register is a national register that records vaccines given to people of all ages in Australia. An example of the information we may request and receive is provided below.

We will use this information to understand how childhood immunisation may be protective against certain conditions, such as allergy. We will also assess what prescription medications are used in relation to childhood conditions, such as asthma, ADHD and autism. All aspects are optional and will not impact you or your child's access to health care.

### An example of the information that may be included in your Medicare claims history:

DATE OF SERVICE	ITEM NUMBER	ITEM DESCRIPTION	SCRAMBLED ORDERING PROVIDER NUMBER*	SCRAMBLED RENDERING PROVIDER NUMBER*	DATE OF REFERRAL	ITEM CATEGORY
20/04/09	00023	Level B consultation	999999A	999999A	20/04/09	2

In accordance with 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 and your child. Please contact us if you would like to access this information.

We are requesting your permission to perform data linkage with the following databases:

- > **The Pharmaceutical Benefits Scheme (PBS)**  
information on prescribed medication
- > **Medicare Benefits Schedule (MBS)**  
information on the use of health services
- > **Australian Immunisation Register (AIR)**  
information on immunisation

For children under 14 years of age, as their parent/guardian, you are responsible for consenting on their behalf. Once your child turns 14 years of age, they will need to complete and sign the participant consent form themselves.



## BIS mother's records

Evidence from BIS and other studies suggests that women's gut bacteria during pregnancy play a crucial role in healthy development of babies. Courses of antibiotics are one of the most important factors influencing the composition of gut bacteria, also known as the gut microbiome. For these reasons, we are interested in obtaining data from the Pharmaceutical Benefits Scheme (PBS) for the BIS child's biological mother medication use. Specifically we are requesting permission to access records for the 3 years prior to the birth of your BIS child and the 12 months following birth.

Using PBS records we can get accurate information about the exact type and timing of medications, such as antibiotics. This will allow us to study whether women's exposure to antibiotics influences the health of their baby by altering the gut microbiome before, during or after pregnancy.



The consent form is sent securely to the Services Australia, or data linkage unit, who holds MBS, PBS and AIR data confidentially.

## How is my information protected?

Maintaining the confidentiality of your family's data is extremely important to the BIS team. When you joined BIS, we allocated you a BIS ID number - a four digit number such as 'C0000'. BIS researchers only see your BIS ID number, not your name or other identifying information. The only people who will have access to identifying information are the BIS personnel, who schedule and conduct your visit.

There are laws designed to protect the confidentiality of administrative data. The information obtained by data linkage is stored securely within each agency, and access to the data is controlled by a data custodian. As with all BIS activities, we must get approval from Barwon Health's Human Research Ethics Committee (HREC) to undertake this research.

Under no circumstances will we forward identified information to other researchers, organisations or individuals.



# Storage, retention and destruction of your information

By signing the consent form, you are consenting to the BIS research staff collecting and using 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 you and your child will be used in publications such as 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.

With your permission, the data collected in BIS will be stored and linked to the BIS research database for future use. The data will be stored securely within the main dataset, and will be destroyed at the same time the main data is securely destroyed, which isn't likely to be for many years.

Data collected in the BIS may be used for a range of future projects. It is not possible for us to specify what these projects will be, because as scientific knowledge evolves, the important scientific questions change and new health challenges arise. All future research using BIS data will need to be approved by the BIS Steering Committee and the Hospital Research and The Human Research Ethics Committee at Barwon Health.

If you give consent for your child's data to be used in this research project, we will store data at least seven years beyond your child's 18th birthday.

## Important note:

If you do not wish to consent for BIS to access you and/or your child's Commonwealth records, please complete and indicate this on the online consent form. Please note this will not exclude you from being invited to participate in other BIS research projects in the future.



## What do we need from you?

### What can you do?

- > You will receive an email with a link to the online consent form.
- > If you are happy with the information you are provided in this brochure, please follow this link. Otherwise, in the coming weeks we will be in contact with you to discuss this project and answer any questions.
- > Within the online consent form, please select which Commonwealth records you do/do not consent for use in this research project.
- > Alternatively you can request to complete the BIS Data Linkage consent form as a hardcopy form and return to BIS via a reply paid envelope.



## Stay in the loop!

**Keep up-to-date** with the BIS study findings and share fun facts with your BIS kid via our Facebook page <https://www.facebook.com/barwoninfantstudy/>

If you have any questions or concerns you can contact us on the BIS mobile: **0400 432 976** or email us at [bis@barwonhealth.org.au](mailto:bis@barwonhealth.org.au)

**We are always happy to hear from you.**

## 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 is also reviewed by the data custodians before granting the Barwon Infant Study approval to conduct data linkage.

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**.

**Thank you for your child and family's valuable contribution to improving the health of our community.**