



HREC Project Number: HREC/17/RCHM/221 Data linkage

Research Project Title: Linkage of The PEBBLES (Prevention of Eczema, Food Allergy and Sensitisation Using a Skin Barrier Improvement Strategy) study to Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS), Australian Immunisation Register (AIR) and Victorian Hospital and Emergency Department Data

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Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to invite your child to participate in a research project that is explained below. This document is 4 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether you would like your child to take part in this aspect of this research project. Please read it carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research is up to you

It is your choice whether or not you and your child can take part in the research – it is completely voluntary. You do not have to agree if you do not want to. If you decide you do not want you and your child to take part, it will not affect the treatment and care your child gets at The Royal Children's Hospital, or from the hospital your child was born in.

We will give you a copy of this information and consent form to keep.

1. What is the research project about?

Thank you for enrolling your child in the PEBBLES research project. In this world-first study, we aim to see if using an emollient cream called EpiCeram™ on the skin of babies will prevent them from developing eczema and food allergy. If we can achieve this, it might reduce the risk of these children developing other allergies later on in life, such as asthma.

We would now like to obtain details about your child's health from the Department of Human Services (DHS) who holds Medicare Benefits Scheme (MBS), Pharmaceutical Benefits Scheme (PBS), Australian Immunisation Register (AIR) data and also the Victorian Department of Health and Human Services (VDHHS), who collects information about presentations to hospitals and emergency departments for medical care in Victoria. Collecting this information will help us to determine if this intervention is cost effective and also allow us to measure outcomes beyond the end of the current study. This information would be very useful to further our research.

For us to obtain details from DHS, we will require you to complete the consent form authorising the study to access your child's complete MBS, PBS, AIR data as outline on the back of the consent form. MBS collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. AIR is a national register that records details of vaccinations given to Australians. The consent form will be sent securely to the DHS who holds this information confidentially. For us to obtain details from VDHHS, we will require you to complete the consent form authorising the study to access your child's complete hospital records.

The specific health data we would like to obtain from **MBS, PBS, and AIR** from the time they are born to when they are 4.5 years of age, is:

Medicare (MBS)

1. Date of service (*Date that the service was rendered by the provider, to the patient*)
2. MBS Item number (*Items Numbers as per the Medicare Benefits Schedule*)
3. MBS Item description (*describes the service as per the Medicare Benefits Schedule*)
4. Provider charge (*the dollar amount the provider charged for the service*)
5. Schedule fee (*fee as listed in the Medicare Benefits Schedule ie: the Governments recommended fee for that service*)
6. Benefit paid (*this is the benefit paid to the patient*)
7. Patient Out of Pocket (*the dollar amount the patient is out of pocket*)
8. Bill type (*the method the benefit was claimed ie, Bulk Bill, Direct bill, Cheque to provider via patient etc.*)
9. Scrambled Ordering Provider Number (*a unique scrambled provider number without identifying the referring provider*)
10. Scrambled Rendering Provider Number (*a unique scrambled provider number without identifying the provider who rendered the service*)
11. Date of referral (*Date that the referral was written by the servicing provider*)
12. Hospital Indicator (*Indication of whether or not the service was provided as private patient in a public hospital or outside of hospital*)
13. Item category (*where the service sits in the hierarchical structure according to the Medicare Benefits Schedule*)

Pharmaceutical Benefits Scheme (PBS)

1. Date of supply (*Date the prescription was supplied by the pharmacy*)
2. Date of Prescribing (*Date that the prescription was prescribed by a Medical Practitioner to a patient*)
3. PBS Item Code (*Items Code reflected in the Pharmaceutical Benefits Scheme*)
4. PBS Item Description (*the item description as noted in the Pharmaceutical Benefits Scheme website*)
5. Patient category e.g. general, concession, safety net, doctor's bag (*Patient's eligibility status at the time of supply*)
6. Patient contribution (*the contribution paid by the patient*)
7. PBS Net Benefit (*Amount paid by the Government*)
8. Scrambled Prescriber Number (*a unique scrambled number without identifying the particular prescriber of the PBS item*)
9. Form Category (*Description of script type*)
10. Anatomical Therapeutic Chemical (ATC) Classification Code (*category of the prescribed drug*)
11. ATC Name (*drug name according to ATC*)

Australian Immunisation Register (AIR)

1. Schedule (*recommended age for immunisation*)
2. Immunisation (*type of immunisation*)
3. Date given (*date immunisation received*)
4. Brand name given (*name of vaccine*)

The specific health data we like to obtain from the **Victorian DHHS**, from the time they are born to when they are 4.5 years of age will include details of your child's hospitalisations and ED visits such as diagnosis, length of stay and its costs.

This project within the PEBBLES Study has been approved by Human Research Ethics Committees at Royal Children's Hospital. With your consent, we will provide your identifying information (your name, address, date of birth, country of birth and Medicare care number) to **the Department of Human Services (DHS)** and the **Victorian DHHS**. Based on only this identifying information, these organisations will identify the health related data they hold about your child and release, to the PEBBLES researchers which is consistent with the aims of this research project.

What will I be asked to do?

Should you agree to participate, you would be asked to sign two consent forms and to provide your child's Medicare number, and the hospital that your child was born in. If your child is on more than one Medicare card, all Medicare card numbers will be recorded on the consent form and the signature of the primary card holder obtained.

How will my confidentiality be protected?

Your child's MBS, PBS, AIR and hospital information will not be reported in a way that isolates your child as an individual. Results will be grouped together, summarised and not identify your child in any way.

The collected information will be stored secure at the University of Melbourne in locked filing cabinets or in restricted access folders on the Institute's network drive and will only be accessible to the research team. This research information will be destroyed when a participant turns 25 years old or 15 years following the study closure - whichever date is latest. Any information we collect that can identify your child will be treated as confidential and used only in this project unless otherwise specified. The information will be re-identifiable. This means that we will remove your child's name and give the information a special code number. Only the research team can match your child's name to their code number, if it is necessary to do so.

We will present these results at scientific conferences and publish them in scientific journals. The results will not identify any individuals, only group information will be presented.

How will I receive feedback?

A summary of results will be made available to you at the end of this project.

Will participation in this study impact on me in any way?

Your child's participation in this, and all PEBBLES projects, is completely voluntary. Should you wish to withdraw at any stage, or to withdraw any unprocessed data you have supplied, you are free to do so without prejudice. Participation in this project will not impact on your child in any way.

Can I opt out of the study in future?

Yes, you can opt out of this study at any time, and we will remove your child's data. If you would like to do so, please contact us via email (pebbles-study@unimelb.edu.au) or phone (1800 875 127). However, if you wish to withdraw after the data is analysed and deidentified results published, we will not be able to remove your child's information from the results.

Where can I get further information?

Should you require any further information, or have any concerns, please do not hesitate to contact the researchers on the numbers given above. If you have any concerns and/or complaints about the project, the way it is being conducted or your rights as a research participant and would like to speak to someone independent of the project, please contact: the Director, Research Ethics & Governance, The Royal Children's Hospital Melbourne on telephone: (03) 9345 5044.

How do I agree to participate?

If you would like to participate, please indicate that you have read and understood this information statement by signing the two electronic consent forms. We would prefer it if you allowed us to access all of your child's information, and to do so, you need to tick "yes" on the consent form for all options. However, you may choose to grant us permission to access only some of your child's information (tick "yes" for only options). You may also choose to not allow us to access any of your information (tick "no" for all options).

If you would like more information about the project, please contact the Study Coordinator:

Name: Shaie O'Brien

Contact telephone: 1800 875 127

Email: pebbles-study@unimelb.edu.au

If you have any concerns and/or complaints about the project, the way it is being conducted or your rights as a research participant, and would like to speak to someone independent of the project, please contact:

Director
Research Development & Ethics
The Royal Children's Hospital Melbourne
Telephone: (03) 9345 5044.

