INFORMATION SHEET

Study Title:
Generic Biobank for Human Bodily Specimens, to Assess Microbial Pathogens, Commensals, Biomarkers and Immune Responses to Allergens, Bacteria, Vaccine Antigens and Viruses

Investigator: Associate Professor Peter Richmond

Introduction

You and/ or your child are being invited to donate bodily specimens for a generic Biobank of samples to be used in optimising scientific assays by the Vaccine Trials Group or research collaborators of the Telethon Kids Institute.
You or your child's participation in this study is voluntary. It is important that you have all the information that you need before you decide if you want to donate you or your child's bodily specimens. A member of the staff will talk to you about the study and answer any questions you may have. You may also talk to family and friends about your decision. Please take your time making your decision.

Purpose of the Study

The samples taken will be used to develop assays to look at microbial pathogens, commensals, biomarkers and immune responses in specimens, to various bacteria, allergens, vaccine antigens and viral infections.

Who can participate in the study and what will the study involve?

We invite healthy volunteers to participate in this study. You can decide that you or your child do not want to continue with specimen collection at any time.

Samples will be obtained from healthy volunteers from whom we may collect up to 100mL of blood in volunteers >16 years, 2mls saliva, 4 nasopharyngeal swabs, unlimited skin swabs, 100ml urine, and 2 stool samples. Blood samples in children will be aged related: <1 year 10mls, 1-4 years 20mls, 5-8 years 30mls, 9-12 years 40mls, 13-15 years 50mls.
For volunteers >16 years this will mean that the needle will be in your arm during blood collection for approximately 5 minutes.
Numbing cream can be used by the research study staff to reduce discomfort to the area before they take any blood samples.

It will involve the one visit to our clinic in the Clinical Research Suites at Perth Children's Hospital or where appropriate sample collection at community events. There will be no follow-up visits or questionnaires.

Are there any benefits for me participating in the study?

There is no direct health benefit from you or your child participating in this study. You or your child's samples will allow us to establish new microbiological and immunological laboratory techniques. This will enable further research in understanding the differences in an individual's bacteria and viruses, as well as their immune responses to bacteria, allergens, vaccine antigens and viruses.

Are there any risks, inconveniences or discomfort to me?

Blood:
Staff trained in venepuncture procedure will take you or your child's blood using an aseptic (infection preventing) technique. Blood sampling may cause temporary discomfort. The amount of blood to be taken will not cause any symptoms or anaemia. There may be slight bruising at the site where the blood was taken, however this should subside in a few days.

The procedure may cause fainting or a feeling of 'light headedness'. If you or your child are susceptible to fainting during procedures such as these, we will ask that you or your child lie on the treatment bed. If required, a light refreshment will be offered prior to you or your child leaving the study site.

Nasopharyngeal Swabs:
Staff trained in nasopharyngeal swabbing will perform the procedure. A slight discomfort may be felt during and after the procedure and is often likened to "a tickle" in the back of the nose, which will pass after a couple of minutes.

Skin, saliva, Urine and Stool samples:
May be self-collected and pose no risks, inconvenience or discomfort to the individual.

Confidentiality and Privacy of Information

Confidentiality will be maintained at all times. We will collect some basic medical information regarding presence of allergic conditions, current medications being taken and existence of any chronic medical problems. We will also collect information on age. If you do not wish to provide this information, you may withdraw from the study without specifying the reason. Your signed consent form and any identifying information will be kept in a locked filing cabinet in an office at the Vaccine Trials Group and electronic files will be password protected.

You or your child's samples will be de-identified, numerically coded and stored in a freezer and liquid nitrogen at the Perth Children's Hospital. Access to these areas is only by a security key card. You or your child's sample will be only used for the purpose of this study. Any identifying information is stored separately.

All clinical study records will be kept for a minimum of 15 years as mandated by the Therapeutic Goods Administration (TGA) the Australian regulatory body. In addition, study

records related to your infant will be kept until they reach 25 years of age as per local guidelines. No genetic testing will be performed.

Research data gathered from the results of this study may be published, however no identifying information will be used.

Compensation

If you or your child become ill or injured as a result of participation in this study, appropriate medical treatment will be provided. Associate Prof. Peter Richmond, the Principal Investigator, can be contacted on 0400 450 240 for information. You or your child will not be paid for your participation in this study. You or your child's rights to compensation under statute or common law are maintained.

Travel Costs

You may be reimbursed for parking costs at the centre if invited to the clinic for sample collection.

External Collaborators

With your consent, samples may be sent to and used by other groups outside of the Vaccine Trials Group, Telethon Kids Institute. Extra samples sent to collaborators may be destroyed by the external collaborator.

Other Information

You are encouraged to ask questions at any time during the study and your consent to participate can be withdrawn at any time. If you have a problem or have more questions about the study please call Associate Professor Peter Richmond at 0400 450 240. If you have questions about your rights or the manner of conduct of the study, you may contact the Executive Director of Medical Services, Perth Children's Hospital on (08) 6456 2222.

Ethics Approval for this study

This study has been reviewed and approved by the Child and Health Service Human Research Ethics committee.

FORM OF CONSENT

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE

I, …….....……
Given Names SURNAME

Date of Birth: _____

have read the information of the study titled:

GENERIC BIOBANK FOR HUMAN BODILY SPECIMENS, TO LOOK AT MICROBIAL PATHOGENS, COMMENSALS, BIOMARKERS AND IMMUNE RESPONSES TO ALLERGENS, BACTERIA, VACCINE ANTIGENS AND VIRUSES

I have read and understood the information given to me and any questions I have asked have been answered to my satisfaction. I understand that my samples will be used to create a Biobank that the Telethon Kids Institute, Vaccine Trials Group, would draw from to look at microbial pathogens, commensals, biomarkers and immune responses to allergens, bacteria, vaccine antigens and viruses.

I agree that research data gathered from the results of this study may be published, provided that no identifying information is used.

I understand I may withdraw from the study at any stage and withdrawal will not interfere with routine care or my employment status.

I agree that my samples can be sent to and used by external collaborators.
☐Yes ☐No

PARTICIPANT'S SIGNATURE: …….

Dated: …….. day of …….. 20…

I,…….
(Research Assistant/Dr/Nurse)

have explained the above to the signatory who stated that he/she understood the same.

SIGNATURE: ……

Dated: …….day of ……. 20…

FORM OF CONSENT (For Parent/Guardian)

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE

I, …….....……
Given Names SURNAME

have read the information of the study titled:

GENERIC BIOBANK FOR HUMAN BODILY SPECIMENS, TO LOOK AT MICROBIAL PATHOGENS, COMMENSALS, BIOMARKERS AND IMMUNE RESPONSES TO ALLERGENS, BACTERIA, VACCINE ANTIGENS AND VIRUSES

I have read and understood the information given to me and any questions I have asked have been answered to my satisfaction. I understand that my child's samples will be used to create a Biobank that the Telethon Kids Institute, Vaccine Trials Group, would draw from to look at microbiological pathogens, commensals and immunology responses to allergens, bacteria, vaccine antigens and viral infection.

I agree to allow.....
(full name of participant and relationship of participant to signatory)

Date of Birth: _____
to participate in the study.

I agree that research data gathered from the results of this study may be published, provided that no identifying information is used.

I understand I may withdraw my child from the study at any stage and withdrawal will not interfere their routine care or employment status.

I agree that my child's samples can be sent to and used by external collaborators.
☐Yes ☐No

PARTICIPANT'S SIGNATURE: …….

Dated: …….. day of …….. 20…

I,…….
(Research Assistant/Dr/Nurse)

have explained the above to the signatory who stated that he/she understood the same.

SIGNATURE: ……

Dated: …….day of ……. 20…