Government of **Western Australia**
**Child and Adolescent Health Service**

THE UNIVERSITY OF WESTERN AUSTRALIA

# Parent/Guardian Information Sheet & Consent Form – Control Group

**Perth Children's Hospital**

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|---|---|
| **Title** | **C**hildhood **H**ealth and **I**mmunity **P**ost-burn: Assessing the immune response to vaccination following a burn injury |
| **Short Title** | The **CHIP** study |
| **Coordinating Principal Investigator/ Principal Investigator** | Associate Professor Mark Fear, Professor Fiona Wood, Professor Peter Richmond |
| **Associate Investigator(s)** | Dr Lucy Barrett, Professor Suzanne Rea, Dr Helen Douglas, Dr Alison McDonnell, Dr Lisa Martin, Dr Ruth Thornton, Dr Christian Tjiam |
| **Location** | Perth Children's Hospital, Burn Injury Research Unit (located at Harry Perkins Institute of Medical Research Nedlands), Telethon Kids Institute |

## Part 1: What does participation involve?

### 1 Introduction

We would like to invite your child to take part in a research project titled *"**C**hildhood **H**ealth and **I**mmunity **P**ost-burn: Assessing the immune response to vaccination following a burn injury"*.

This project aims to understand the long-term health impacts of burn injury on the immune system, with the aim of identifying patients who may have immune deficiencies as a result of their burn injury. We also require a group of healthy, uninjured children to participate in this study so that we have a comparison group. This will be explained in more detail below.

This 'Participant Information Sheet' tells you about the research project. It explains the tests and requirements involved in participating. Knowing what is involved will help you decide if you and your child want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not your child takes part in this study, you might want to talk about it with a relative, friend or local doctor. Participation in this research is voluntary. If you and your child do not wish to take part, you do not have to.

If you decide you would like your child to take part in the research project, you will be asked to sign the consent section of this form. By signing it you are telling us that you:

- Understand what you have read
- Consent to your child taking part in the research project
- Consent to your child undergoing the tests that are described
- Consent to the use of your child's personal and health information, as described

You will be given a copy of this 'Participant Information and Consent Form' to keep.

## 2 What is the purpose of this research?

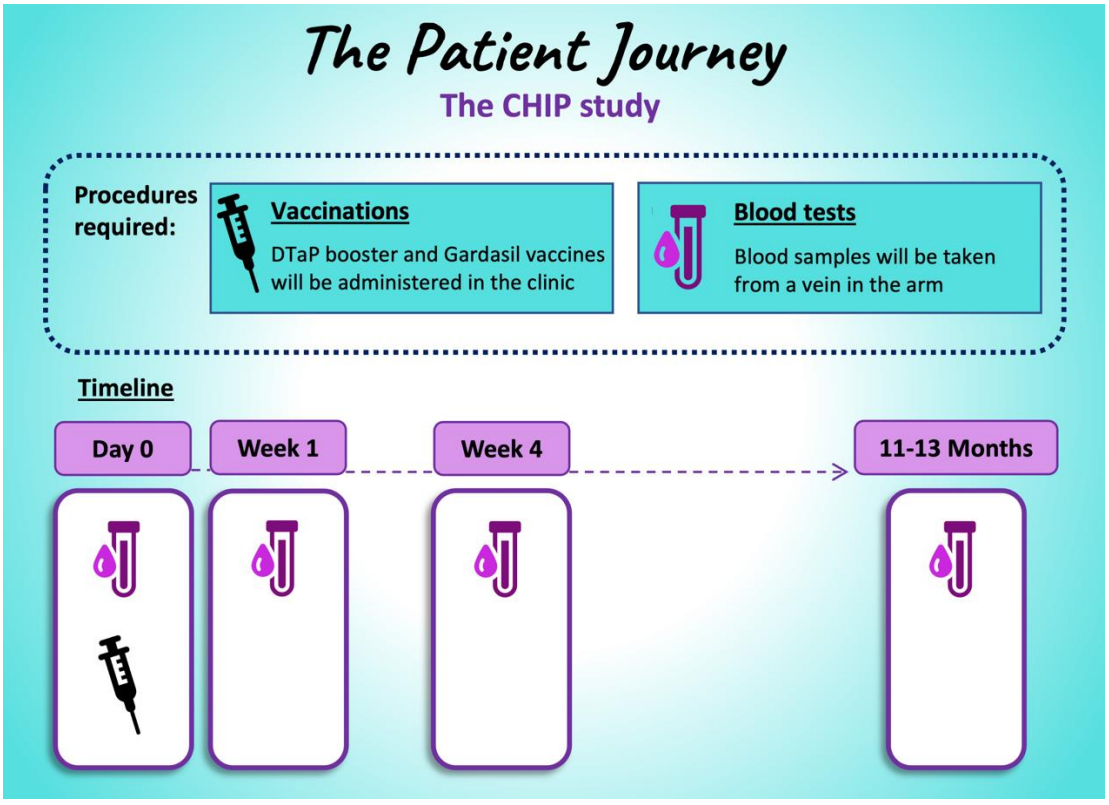
Previous research in children with burn injuries indicates that burn injury can impact the immune system, causing it to not function as well as it should. In our previous study, blood samples taken from children who had previously received their Diphtheria, Pertussis and Tetanus vaccine (**DTaP vaccine**), which is standard for all children at Age 4 as part of the Australian Immunisation program, showed that some children with burn injuries did not have the expected level of protection for these preventable diseases, even though they had been vaccinated.

We are conducting this study in order to understand how a burn injury can affect the immune system long-term. We hope this will enable us to identify patients who may have a dysfunctional immune system after their burn injury, and subsequently develop treatments to help these patients return their immune system function back to normal. This will ensure people with burns do not suffer long-term health consequences as a result of their burn, and make sure vaccinations give the expected protection to prevent infections. We require a cohort of healthy, uninjured children to participate in this study to compare to so we can investigate the impact of a burn on immunity.

This research has been initiated by Professor Fiona Wood and the research team at the Burn Injury Research Unit, with funding by the Fiona Wood Foundation and the WA Child Health Research Fund.

## 3 What does participation in this research involve?

If you agree for your child to take part in this study, we will take a baseline blood sample from your child following which they will receive a standard dose of a **DTaP booster vaccine** as well as the **Gardasil vaccine.** All children are due to receive these vaccines in Year 7 at school, so participating in this study means your child will be up to date with their vaccinations and do not need to receive them at school. We require additional blood samples to be taken 1 week and 4 weeks after vaccination in the clinic, which will allow us to track the vaccine response by analysing the cells in the blood. Finally, we request that you and your child come in for a fourth blood sample to be taken between 11-13 months after your child's vaccinations. These four blood samples will allow us to look immune cell functions before and after vaccination, and to see if this changes over the 12-month period. Each blood sample will be around 40ml (4 tubes).



This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.
There are no costs to you or your child for this research project, nor will you or your child be paid. Parking vouchers will be provided for each visit to the hospital, and a $50 cash reimbursement for travel costs will be provided to you at the final visit.

**4 What do I have to do?**

If you agree for your child to take part, we will need you to consent to your child receiving the DTaP booster and Gardasil vaccinations, give a blood sample at that time, and then for your child come in 1 week, 4 weeks and 12 months after this appointment to give blood samples for our study.

**5 Other relevant information about the research project**

The study is exclusive to Perth Children's Hospital. To analyse the results we will also collect some details about your child such as age, gender, and previous medical history. This will only be information relating to relevant medical conditions and vaccination history. We need this information so we can understand how patient factors influence the data we collect, and determine if your child can participate according to our guidelines. Data collected will be stored in a Redcap database and analysed by the research team. It will be deidentified so that any research uses a study ID, not identifying information. The Chief investigator will keep a separate file that can link the study ID to your child. This will be used if you want to withdraw from the study. The data will be used to develop a profile of immune function after burn injury in comparison to a healthy control cohort, and to identify at-risk burn patients who may need additional treatment to boost their immune function.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you and your child do not wish to take part, you do not have to. Your decision regarding your participation at any stage of the study will not affect your relationship with Perth Children's Hospital. If you do decide to take part, you and your child will be given this 'Participant Information and Consent Form' to sign and you will be given a copy to keep.

**7 What are the alternatives to participation?**

You and your child do not have to take part in this research project.

**8 What are the possible benefits of my child taking part?**

There are no direct benefits to you and your child from taking part in this research. However, we do believe the information we gain from this study will benefit patients with burn injuries in the future by ensuring people who have underlying immune problems as a result of their burn get appropriate care and follow-up.

**9 What are the possible risks and disadvantages of my child taking part?**

Some discomfort may be felt during blood collection. The vaccines being given in this study have been shown to be safe and efficacious and will be administered to year 7 students at school, so this will not be an extra vaccination for your child but will replace the school administered one. If your child has had a previous reaction to the DTaP vaccine your child will not be eligible for this study. Risk of adverse vaccine event (rare, and will be informed by the presence of any previous adverse event in the patients) include redness, pain, and swelling at the injection site (common), while uncommon adverse events include headaches, fatigue, fever, and swelling of the limb. It should be noted, that while this study is looking at vaccine responses, this is in regards to the immune cells developing protection to the diseases targeted by this vaccine (whooping cough, tetanus, and diphtheria), and not related to adverse events. Data from our studies in children with burns indicates that a burn injury does not increase the chance of adverse events as a result of the DTaP vaccine.

**10 What will happen to my child's samples?**

The blood samples taken will be processed to extract immune cells and plasma, which will be stored for analysis. The samples will only be used for this project by the research team. They will not be provided to other groups. The samples collected and the data from this study surgery will all be de-identified before analysis. Your child's name will be removed from the samples and data and replaced by a study code. This means that staff in the laboratory will not be able to identify who gave the samples and the information stays confidential.

**11 Can my child have other treatments during this research project?**

As we are looking at the immune system, your child will not be able to take part in this study if they are taking immunosuppressive drugs or antibiotics. There are no other restrictions on any treatments that your child might receive if you choose to take part in this project, and no restrictions on medications after the study has begun.

**12 What if I withdraw my child from this research project?**

You can withdraw your child from this study at any time. If you withdraw them prior to the first blood collection no data will be collected. If you withdraw them after the second blood collection the blood samples will be retained. You will have the option to withdraw blood samples collected from your child pre- and post-vaccination for no further analysis to occur.

**13 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include changes in our funding or significant staff changes.

**14 What happens when the research project ends?**

The results from this study will be used to develop a greater understanding of immune function and response to vaccines after a burn injury. We hope this will enable us to screen burn patients during and after burn healing, to identify patients who may need extra treatments to restore their immune function back to normal.

**15 What will happen to any information collected?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about your child for the research project. Any information obtained in connection with this research project that can identify your child will remain confidential. Your child's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Any data collected for this research will be stored for at least 15 years before being destroyed. The data will be kept securely in a REDCAP database on WA Health servers. Deidentified data for analysis may also be stored on University of Western Australia servers in password protected files. Information about your child may be obtained from their health records held at this health service for the purpose of this research. By signing the consent form you agree to the research team accessing health records for your child if they are relevant to participation in this research project. It is anticipated that the results of this research project will be published and/or presented at a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your permission.

Information about participation in this research project may be recorded in your child's health records. In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about your child. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your child's information. Any information obtained for the purpose of this research project that can identify your child will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## 16 Who is organising and funding the research?

This research project is being conducted by the Burn injury Research Unit at the University of Western Australia (UWA) together with Telethon Kids Institute and the Burns Service WA, and is being funded by the Fiona Wood Foundation and the WA Child Health Research Fund. By consenting to taking part in this research project, you agree that samples collected from your child (or data generated from analysis of these materials) may be provided to the Burn Injury Research Unit at UWA. This research team is located in the Harry Perkins North institute at Sir Charles Gairdner Hospital campus. You and your child will not benefit financially from involvement in this research project even if, for example, the samples or knowledge acquired from analysis of the samples, prove to be of commercial value to the Burn Injury Research Unit at UWA. Intellectual property acquired from this study will remain the property of the Burn Injury Research Unit at UWA. There will be no compensation to study participants or their families. In addition, although future commercialisation is unlikely, if knowledge acquired through this research leads to discoveries that are of commercial value there will be no financial benefit to you or your family from these discoveries. No member of the research team will receive a personal financial benefit from your child's involvement in this research project (other than their ordinary wages). There are no conflicts of interest to declare. Results will be shared via academic journals, conferences and presentations.

## 17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Child and Adolescent Helath Service HREC (RGS5988). This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people and families who agree to participate in human research studies.

## 18 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if your child has any medical problems which may be related to involvement in the project, you can contact any of the following people:

**Clinical contact person**

| | |
|---|---|
| Name | Professor Fiona Wood |
| Position | Director of the Burn Service |
| Email | Fiona.Wood@health.wa.gov.au |
| Telephone | 08 6456 2222 |

**Complaints Contact person**

If you have any concerns or complaints regarding this study, you can contact the Executive Director Medical Services via hospital switchboard PCH (Tel: 6456 2222). Any concerns will be drawn to the attention of the Ethics Committee.

# Consent Form

| | |
|---|---|
| **Title** | Understanding the lifelong impact of paediatric burns on health: Assessing the immune response to vaccination following a burn injury |
| **Short Title** | Vaccine responses in patients with burn injury |
| **Protocol Number** | Version 4 – 03/09/2024 |
| **Chief Principal Investigator** | Associate Professor Mark Fear |
| **Principal Investigator** | Professor Fiona Wood, Dr Mark Fear, Professor Peter Richmond |
| **Associate Investigator(s)** | Dr Lucy Barrett, Professor Suzanne Rea, Dr Helen Douglas, Dr Alison McDonnell, Dr Lisa Martin, Dr Ruth Thornton, Dr Christian Tjiam |
| **Location** | Perth Children's Hospital |

**Declaration**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
I understand the purposes, procedures and risks of the research described in the project.
I have had an opportunity to ask questions and I am satisfied with the answers I have received.
I freely agree to my child participating in this research project as described and understand that I am free to withdraw my child at any time during the project without affecting their future health care.
I understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Burn Injury Research Unit concerning my child's medical and vaccination history for the purposes of this project. I understand that such information will remain confidential.

Name of participant (please print) _____

Name of parent or guardian _____

Signature of parent or guardian _____ Date _____

Name of Witness* to Signature (please print) _____

Signature _____ Date _____

* Only required in specific circumstances Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9.
Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature

# Form for Withdrawal of Participation

| | |
|---|---|
| **Title** | Understanding the lifelong impact of paediatric burns on health: Assessing the immune response to vaccination following a burn injury |
| **Short Title** | Vaccine responses in patients with burn injury |
| **Protocol Number** | Version 4 – 03/09/2024 |
| **Chief Principal Investigator** | Associate Professor Mark Fear |
| **Principal Investigator** | Professor Fiona Wood, Professor Peter Richmond |
| **Associate Investigator(s)** | Dr Lucy Barrett, Professor Suzanne Rea, Dr Helen Douglas, Dr Alison McDonnell, Dr Lisa Martin, Dr Ruth Thornton, Dr Christian Tjiam |

**Declaration by Participant**

I wish to withdraw my child from participation in the above research project and understand that such withdrawal will not affect my child's treatment or relationship with Perth Children's Hospital.

After withdrawal I want the samples collected to be destroyed (delete as appropriate)

Yes No

Name of participant (please print) _____ _____

Name of parent/ guardian _____

Signature of parent/ guardian _____ Date _____

*In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the parent/guardian of the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.