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

THE UNIVERSITY OF WESTERN AUSTRALIA

Participant Information Sheet/Consent Form – Burn Injury Group

Perth Children's Hospital

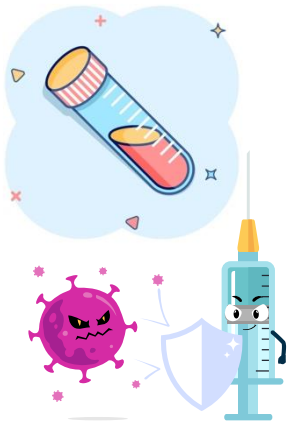
Title	**C**hildhood **H**ealth and **I**mmunity **P**ost-burn: Assessing the immune response to vaccination following a burn injury
Short Title	The **CHIP** study
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Mark Fear, Prof Fiona Wood, Professor Peter Richmond
Associate 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

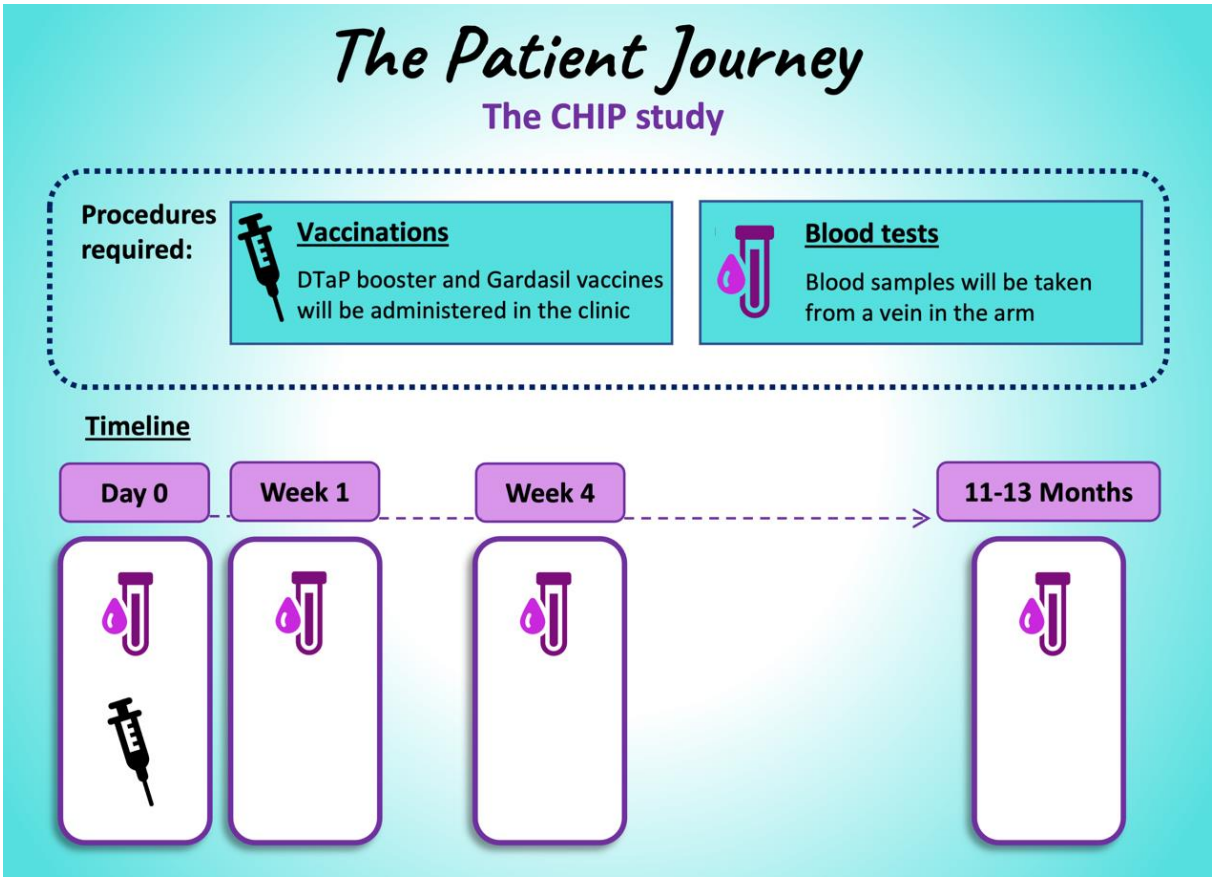
The CHIP study wants to investigate how a burn injury impacts your immune system. Your immune system is made up of white blood cells ("immune cells"), which are important for fighting off invaders like viruses and bacteria that can make you sick. They are also activated when you get a burn injury, as they come in and help heal your burn. You can see your burn healing on your skin, but we also want to know if your burn is causing the immune cells inside your body to be stressed out. We want to make sure that your immune cells are working properly after your burn, so they keep protecting you and make sure you are healthy after your burn has healed.

To do this study and look at how well your immune system is working, we want to look at your white blood cells before and after you get your Year 7 vaccinations. Vaccines are given to you to help your immune system develop protection against diseases, so if you do get infected with a virus or bacteria, your immune cells are ready to fight the nasties off and help you to not get sick. By looking at your blood cells we can see if the vaccines you get are working properly and make sure that your immune cells are ready to fight the invaders if they try to come into your body.

What you need to do if you want to do this study:

All kids going into Year 7 in WA get two vaccines: One that protects against Tetanus, Whooping cough and Diphtheria, and one that protects against a virus that causes cervical cancer. If it's ok with you, we will take a blood sample from you and then you will receive these two vaccines in the clinic at Perth Children's Hospital instead of at school. We also would like to take more blood samples 1 week and 4 weeks after you get your vaccinations, which will allow us to see how well the vaccines worked in your body by analysing the cells in your blood. Finally, we ask that you come in for a fourth blood sample between 11-13 months after your vaccinations. These four blood samples will allow us to look at your immune cells before and after vaccination, and to see if this changes over the 12-month period.





If you agree to take part, we will need you to consent (say yes) to receiving the two vaccinations in the clinic, give a blood sample at that time, and then to come in 1 week, 4 weeks and 11-13 months after this appointment to give blood samples for our study. Each sample will be around 40ml (4 tubes) of blood). Overall, we plan to recruit 30 burn injured kids to take part in this study. To analyse the results we will also collect some details about you from your medical records about your burn (such as body site and size) as well as your age/gender and vaccination history. Your information will be kept private and if you want to withdraw from this study we will get rid of your information if you want. Participation in any research project is voluntary. If you do not wish to take part, you do not have to. You can withdraw from this study at any time and your burn care will not be impacted. There are no direct benefits to you from taking part in this research, but we hope the results from this study will benefit kids with burn injuries in the future by making sure kids whose immune system isn't working as well as it should because of their burn get help and treatment to strengthen their immune system.

If you are worried at all after taking part in this study you can let the research team know and they will help. Or if you don't want to do that you can contact Kid's Helpline on 1800 55 1800 or visit https://headspace.org.au/ where you can find online contacts and information that may help.

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 1 – 03/05/2023
Chief Principal Investigator	Associate Professor Mark Fear
Principal Investigator	Professor Fiona Wood, Dr Peter Richmond
Associate Investigator(s)	Dr Lucy Barrett, Professor Suzanne Rea, Dr Helen Douglas, Dr Alison McDonnell, Dr Lisa Martin, Professor Peter Richmond, 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 participating in this research project as described and understand that I am free to withdraw at any time during the project without affecting my 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 about my burn and treatment for the purposes of this project.
I understand that such information will remain confidential.

Name of participant (please print) _____

Signature of Participant _____ 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 3 – 08/01/2024
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 from participation in the above research project and understand that such withdrawal will not affect my treatment, relationship with those treating me 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) _____

Signature of Participant _____ 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.

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 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.