Government of Western Australia
Child and Adolescent Health Service

THE UNIVERSITY OF WESTERN AUSTRALIA

Participant Information Sheet/Consent Form - Parent/Guardian

Title	Platelet dysfunction and cardiovascular disease following paediatric burns
Coordinating Principal Investigator/ Principal Investigator	Dr Mark Fear, Professor Fiona Wood
Associate Investigator(s)	Dr Matthew Linden, Dr Blair Johnson, Dr Lisa Martin, Dr Andrew Haynes, Professor Daniel Green
Location	Perth Children's Hospital, Burn Injury Research Unit (located at Harry Perkins Institute of Medical Research, Nedlands), Cardiovascular Research Group (University of Western Australia)

Part 1 What does participation involve?

1 Introduction

Because you have come to the Burns Unit at Perth Children's Hospital for your child's treatment we would like to invite the child in your care to take part in this research project, investigating *platelet dysfunction and cardiovascular disease following paediatric burns*. The research project is aiming to identify how a burn injury impacts the function of platelets and blood vessels so that we can better understand why some children go on to develop cardiovascular disease after their injury.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want the child 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 the child can take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish for the child to take part, they do not have to. They will receive the best possible care whether or not they take part.

If you decide you want the child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to the child taking part in the research project

• Consent to the child having the tests and research that are described

• Consent to the use of the 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?

When we look at population health outcomes over many years we have discovered that children (and adults) who have a burn injury are more likely to develop cardiovascular disease (also known as heart disease) in the years following their injury. This study aims to understand why some children experience cardiovascular disease after a burn so that we can create treatments that prevent the disease from developing.

There are two types of cells that are very important in the development of the kinds of cardiovascular disease we see after a burn injury: platelets, and endothelial cells (which line the walls of blood vessels). When activated by injury or inflammation, these two types of cells work together in a way that can cause more inflammation and scaring, called atherosclerosis. We would like to know if a burn injury is increasing the amount of activation in platelets and endothelial cells.

We already know from our work with adult burn patients that burn injuries do appear to increase the sensitivity of platelets to activation. However, platelets from adults and children are already known to be slightly different in how they respond to stimulation, so it's important that we don't just rely on the data from adults. We currently expect that platelets from children will respond in a similar way after a burn.

We will also be using non-invasive ultrasound to assess the function of the endothelial cells so that we can determine the likelihood that platelet-endothelial interactions are contributing do cardiovascular disease risk.

This research has been initiated by Professor Fiona Wood and is a collaboration between the University of Western Australia's Burn Injury Research Unit (lead by Professor Fiona Wood) and the Cardiovascular Research Group (lead by Professor Daniel Green). It is funded by a Telethon research grant and the Fiona Wood Foundation.

3 What does participation in this research involve?

If you agree for your child to take part in this study, we will arrange for you to attend a 45min appointment at Perth Children's Hospital and/or UWA's School of Exercise and Sport Science (approximately 5 minutes down the road from PCH) **four weeks** and **six weeks** after their injury in order to do the following:

- Provide a blood sample (approximately 5.4mL, or about a teaspoon of blood).
- A measurement of flow-mediated dilation of a blood vessel in the arm. This test uses non-invasive high-resolution ultrasound to assess the function of the arteries in the upper arm (brachial artery). Images of the artery in the upper arm will be obtained using an ultrasound probe, whilst a blood pressure cuff is placed around the forearm. After obtaining a resting baseline measurement, the cuff is rapidly inflated to a relatively high pressure which is maintained for exactly 5 minutes, after which the cuff is rapidly deflated and the response is recorded for 3 minutes after cuff deflation.
- Allow us to collect clinical data recorded during your child's treatment for a burn injury. These will be sourced directly from hospital records by clinical staff and will be de-identified before being released to researchers. This will only be information relating to their burn, such as body site and size, as well as age/gender, and other relevant medical records including medications. We need this information so we can understand how patient factors influence the data we collect.

Optional

- Provide a hair sample, which is collected from the back of the head towards the neck. Approximately 100 strands are collected (an area roughly 5mm in diameter), and we aim to minimise the visibility of the collection site. These samples are used to measure the levels of the stress hormone cortisol and other small molecules that are trapped in the hair as it grows.

- Provide a urine sample, which is used to measure biproducts of metabolism that are filtered out of the blood and accumulate in urine.

We will ask about any medications your child is currently taking, and inform you if any are grounds for exclusion from this project (due to an impact on platelets, the heart, or blood vessels). Your child will not be asked to stop taking any prescribed medications. However, we will ask that for the duration of the study period that you avoid giving your child **ibuprofen** (the active ingredient in Nurofen and some other pain relief medications) or **aspirin**, as these common over-the-counter medications can interfere with platelet function. Paracetamol is fine to use for general pain relief (ie: Panadol). If you intend to start your child on any new medications during the study period we would ask that you inform the study doctor.

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 participating in this research project, nor will you or your child be paid. You may be reimbursed for any parking or reasonable travel costs (eg: taxi), though free parking will be available at the UWA site.

4 Does the child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for the child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

Your decision whether the child can or cannot take part, or take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them or relationship with Perth Children's Hospital and the Burns Service of WA.

5 What are the possible benefits of taking part?

There will be no clear benefit to the participant from their participation in this research. However, we believe that the outcomes from this study will allow us to design better treatments for future burn patients to prevent the development of cardiovascular disease.

6 What are the possible risks and disadvantages of taking part?

Some discomfort might be experienced during blood collections and may result in minor bruising around the collection site. A needle slightly wider than what is normally used for children is required (0.81mm outer diameter, rather than 0.65mm). If you are concerned about pain experienced during the collection, you can request the use of Emla cream (a local anaesthetic) prior to collection.

The pressure induced by cuffs during the ultrasound test may cause mild discomfort in the hand, fingers, forearm and/or thigh. Your child will feel a 'squeeze' similar to that of routine blood pressure assessment, and possible 'numbing' or 'tingling' sensation in the hand, fingers and/or forearm. These sensations resolve rapidly following cuff deflation, and your child will be informed ahead of time to minimise any distress this might cause. If your child expresses pain, we can stop the test at any time.

Some children may also be uncomfortable providing a hair or urine sample. Collection of these samples is optional, and you or your child may decline to provide these samples if preferred.

7 What will happen to the participant's test samples?

The blood samples taken will be analysed in the Burn Injury Research Unit labs (UWA) to assess your child's platelet responsiveness to stimulation, and to assess how the platelets interact with other cells in the blood. We will also process the blood in order to store plasma and platelets for further analysis. Similarly, if you provided urine and hair samples, these will be stored for laboratory testing.

These samples will be labelled using an anonymised study code, ensuring that no identifiable information is on the sample. Only the study doctor will have access to the database linking your child to the study code to allow for samples to identified and destroyed at your request if you withdraw your child from this study.

Samples will not be provided to external research groups for the purposes of additional studies, however anonymised samples may be processed in external labs (the Australian National Phenome Centre, Murdoch University) to analyse important biomarkers related to cardiovascular disease and platelet function. All samples processed by external labs are either destroyed or returned to us upon the completion of analysis.

Samples will be stored by our lab for the duration of this study, no more than 12 months after collection.

8 What if the participant is withdrawn from this research project?

If you decide to withdraw the participant from this research project, please notify a member of the research team before withdrawal. If you do withdraw consent during the research project, you can request to remove the data already collected and have the samples destroyed if you choose.

9 What happens when the research project ends?

Upon completion of the research project the results will be published in scientific journals and presented as part of scientific meetings. The results will be used to improve our understanding of the impact of burn injuries on platelet function and cardiovascular disease. This may include use in the design of future studies, or in the implementation of new clinical protocols to better screen for, and prevent, cardiovascular disease caused by childhood burns.

The Fiona Wood Foundation regularly publishes newsletters detailing research outcomes, and provides links to studies on their website. Participants will be notified by email when the outcomes from this study become available. You may also be invited to attend community engagement events hosted by the Fiona Wood Foundation where researchers present their findings and are available to answer any questions you might have.

10 What will happen to information about the participant?

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 7 years or until the youngest participant is 25 years, whichever is later, before being destroyed. The data will be kept securely in a REDCAP database on the WA Health servers, and deidentified data for analysis may 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.

11 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). The ethical aspects of this research project have been approved by the HREC of the Child and Adolescent Health Service (RGS6700).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12 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 the participant has any medical problems which may be related to involvement in the project (for example, any side effects), you can contact the principal study doctor:

Clinical contact person

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

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.

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Declaration by Parent/Guardian

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 the child participating in this research project as described and understand that I am free to withdraw them 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 consent to the collection of blood samples for the purposes of this study.

Optional:

I also consent to collection of the following samples:
☐ Hair
☐ Urine

Name of Child (please print) _____

Signature of Child _____ Date _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

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 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, the research project.

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

Form for Withdrawal of Participation – Parent/Guardian

Title	Platelet dysfunction and cardiovascular disease following paediatric burns
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Declaration by Parent/Guardian

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

☐ I request that any samples collected from the child for the purpose of this study be destroyed.

Name of Child (please print) _____

Signature of Child _____ Date _____

Name of Parent/Guardian (please print) _____

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.