PARENT INFORMATION SHEET
Perth Children's Hospital

Evaluating Early Initiation of Hybrid Closed Loop Therapy in Children and Adolescents with a new diagnosis of Type 1 Diabetes

Why are we asking you?

We are asking you and your child to take part in this study because your child has recently been diagnosed with Type 1 diabetes and is aged between 1 - 17 years.

Why are we doing the study?

Hybrid closed loop (HCL) therapy using an insulin pump and a sensor is a recommended strategy for the management of Type 1 diabetes (T1D). Research has shown HCL is safe and effective in improving glucose levels in children and adolescents in research and clinical settings.

The Perth Children's Hospital diabetes department have implemented a newly diagnosed model of care to offer early HCL therapy to children with T1D, as research has shown improved glycaemic control when closed loop is started early from diagnosis of T1D in comparison to standard practice of multiple daily injections.

Due to the expense of accessing and using HCL therapy, not everyone is able to commence this therapy. Access is limited to those with private health insurance, self-funding, or philanthropic programs which can result in a significant gap in equitable access.

The aim of this study is to evaluate real-world implementation of early commencement of HCL therapy in children with T1D in the newly diagnosed period at the Diabetes department at PCH. Overall, the major intention of this study is to analyse the impact of providing the best practice therapy to all individuals diagnosed with T1D in the newly diagnosed period and to advocate for improved access to insulin pump therapy in Australian children moving forward.

Who is carrying out the study?

The study is being carried out by Professor Liz Davis, Dr Kate Lomax, Dr Mary Abraham, Dr Craig Taplin and Professor Tim Jones from the Rio Tinto Children's Diabetes Centre at Perth Children's Hospital and Telethon Kids Institute. We are working with collaborators Professor Sophia Zoungas and Dr Ella Zomer from Monash University and Professor Yvonne Zurynski from Macquarie University. This is a Telethon Kids Institute sponsored study and is supported by the WA State Government and Channel 7 Telethon Trust through a WA Child Research Fund grant.

What will the study tell us?

This study will tell us if using the advanced hybrid closed loop system soon after diagnosis of diabetes is beneficial and how this technology affects how people feel about managing diabetes.

Do you have to take part?

No, you do not have to take part in this study. If you decide to take part and then later change your mind that is ok. It will not change the way your child is treated by your clinic team. You can stop at any time, we just ask that you let us know. The clinic team will continue to support you with your child's diabetes management throughout the study and afterwards regardless of if you take part in the study.

What will you be asked to do if you decide to take part in this study?
Participation involves the completion of questionnaires and allowing us to access and use your child's health and medical information. We are not asking you or your child to do anything else outside of standard of care, other than the questionnaires at the start of the study, at 12 months and 24 months, which is the conclusion of the study. Your child's diabetes management will continue to be provided by the clinical team.

This study will take 24 months. Majority of the data we need for this study is being collected by the clinical team routinely. Where this occurs, we will access this data from your child's medical records so that you don't have to provide it twice. Any extra information we collect will be collected in questionnaires online using REDCap. This can be done in clinic when you attend your child's clinic appointment, or at home.

At pump start, the additional questionnaires will take approximately 25 minutes to complete. Questionnaires at 12 and 24 months will take approximately 40 minutes to complete.

Below is a summary of the data we will look at for this study:

	Description	**Frequency**
Routinely collected in clinic	HbA1c CGM downloads Insulin pump downloads Height, weight Medication Significant events, such as any episodes of severe hypoglycaemia, of Diabetic ketoacidosis (DKA)	Pump start Every 3 months until 24 months post diagnosis
	Questionnaires: Type 1 Diabetes and Life Measure Problem Areas in Diabetes	12- and 24-months post diagnosis
Routinely collected by the hospital	Emergency department attendance Hospital admissions Number of out-of-clinic visits (telephone, telemedicine) Other health professional attendances	From pump start until 24 months post diagnosis
Additional data for the study	Questionnaires: Anxiety: GAD-7 Pittsburgh Sleep Quality Index Quality of Life: Child Health Utility instrument Diabetes Treatment Acceptance and Satisfaction	Pump start, 12- and 24-months post diagnosis
	Questionnaires: Hypoglycaemia Fear Survey	12- and 24-months post diagnosis

What is the likely benefit in participation?

There is no direct benefit to you or your child in participating in this study. will receive any benefits from this study. It is important to see if this new technology, when started early, can improve glucose levels and if people with Type 1 diabetes feel confident using it. If it works, the study may be used to advocate for better access to insulin pumps for all children and adolescents living with T1D.

What are the possible risks?

This is a low risk study with no invasive or painful procedures, and we do not anticipate any risk to you or your child from being involved in this project.

What are the possible discomforts and/or inconveniences?

In the unlikely event that you become upset or distressed from responding to any of the questionnaires, we will be able to supply you with details of where you can access support.

Where is my child's information kept?

Consent and questionnaire data will be collected using the Child and Adolescent Health Service REDCap account which is a secure web platform.

The remaining data will be stored in restricted access computer folders on a secure Department of Health server at Perth Children's Hospital. Deidentified data, that is data without any names or identifying information, will be shared with the members of the study team employed at Telethon Kids Institute, Monash University and Macquarie University for data analysis and publication of the project outcomes.

Data will be stored indefinitely.

What about my child's privacy?

Any information collected for the purpose of this study will remain confidential. That means that we will assign a unique study number to each participant, and this will be used on the data instead of their name.

Any data published, presented from this study and/or shared with collaborators, including Telethon Kids Institute, Monash University and Macquarie University, will not identify your child by name.

Information about your child's participation in this research project will be recorded in their health records. Information about your child may be obtained from your child's health records held at this, and other, health services for the purposes of this research.

Who has approved the study?

The ethical aspects of this research project have been approved by the Child and Adolescent Health Service Human Research Ethics Committee.

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

Who to contact for more information about this study:

If you or your child would like any more information about this study, please do not hesitate to contact the research team. They are very happy to answer your questions.

Telephone contact: 08 6456 8287 (Dr Kate Lomax)
Email: Diabetes.Research@health.wa.gov.au

Who to contact if you have any concerns about the organisation or running of the study?

If you or your child have any concerns or complaints regarding this study, you can contact the Executive Director of Medical Services, at PCH via switchboard, on 08 6456 2222. Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

What to do next if you would like to take part in this research:

If you and your child would like to take part in this research study, please contact the study team on the details above.

THANK YOU FOR YOUR TIME

FORM OF CONSENT
(For Parent/Guardian of Participant)
Perth Children's Hospital

Declaration by Parent

I, ...
Given Names Surname

have read the information explaining the study entitled: ***Evaluating Early Initiation of Hybrid Closed Loop Therapy in Children and Adolescents with a new diagnosis of Type 1 Diabetes***

- I have read the Participant Information Sheet, and understood the information given to me.
- 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 understand that my child may withdraw from the study at any stage, and this will not impact on routine care.
- I consent to my child's participation in this study.
- I agree to the study team accessing data routinely collected by the clinical team and hospital as described in the information sheet.
- I agree that research data gathered from the results of this study may be published, provided that my child is not identified by name.
- I understand that some of the staff working on this study are employed by Telethon Kids Institute, Monash University and Macquarie University and are not employed by the government of Western Australia. These staff are working with the approval of the Child and Adolescent Health Service (CAHS) and will follow all the required policies and procedures and will safeguard the confidentiality of the participant information.

Name of Parent (please print) _____

Signature of Parent _____ Date _____

Name of Child (please print) _____

Signature of Child _____ Date _____

Declaration by 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 Researcher (please print) _____

Signature _____ Date _____