

Participant Information Sheet (for older children)

Study title:	ACCESS-AID Study – Accelerating Care, Capacity and Equity in AID Systems for New Zealanders with Type 1 diabetes	
Locality:	Health New Zealand	Ethics committee ref: 2025 FULL 22346
Study sponsor:	University of Otago, Dunedin	
Lead investigator:	Prof Ben Wheeler & Assoc Prof Ryan Paul	Contact: 027 470 1980

Kia Ora, Kia Orana, Talofa, Malo e lelei, and Hello!

WHY AM I BEING ASKED TO BE IN THE STUDY?

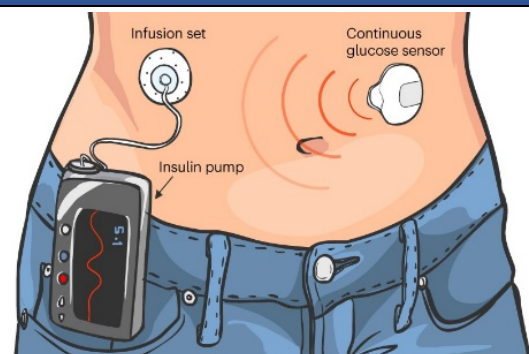
- You have type 1 diabetes or another condition that meets criteria for access to an insulin pump (e.g., Type 3c diabetes).
- You are interested in using a new type of insulin pump what is available.
- In this study, we want to support to start using this insulin pump.
- Your mum, dad, or the person taking care of you and your study doctor will tell you more about being in this study.

DO I HAVE TO BE IN THE STUDY?

No, you don't have to be in this study if you don't want to. You can say YES or NO or change your mind later, even if you have started the study. Even if your mum, dad, or the person taking care of you says YES, you can still say NO. All you have to do is tell your mum, dad, or the person taking care of you or your doctor that you don't want to be in the study. For 3-months whilst in the study, you will be treated for your diabetes by our study team made up of nurses and doctors and other health professionals. After these 3-months you will then be treated for your diabetes by the doctors that see you usually in diabetes clinic.

HOW DOES THE INSULIN PUMP WORK?

You will wear a sensor on your upper arm, tummy or other location you may prefer, and an insulin pump attached to your tummy (as in the picture on the right). The sensor can tell the pump about your blood sugar levels, and the pump can decide how much insulin you need and give you the insulin. The pump can shut off insulin automatically when you go low and give you a correction when you go high.



WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

During your visit to the study doctor or nurse:

- You will answer some questions about you and your diabetes.
- You will be asked to do a little blood test at the beginning at end of the study.
- The doctor/nurse will talk to you and your mum, dad and/or person who looks after you about the new insulin pump and how it will work for you.

- Then you will get a new insulin pump and we will show you how to use it. Your mum, dad, or the person taking care of you will help you to use the pump.
- The doctor/nurse will talk to you often to make sure the new pump is working ok and to ask you any questions.

You will then use the new pump to manage your diabetes. If you become unwell, or the study doctor /nurses concerned about any of your tests, may call you more often. As above, once the doctor/nurse is happy with the new insulin pump and how it is working for you, the study will end and you will continue to see your usual diabetes doctors/nurses.

CAN THE NEW INSULIN PUMP MAKE ME SICK?

There may be changes in the way you feel or in what the doctor/nurse may see when you talk to us. With any insulin pump there can sometimes be side effects. Side effects are unwanted things that can happen to your body after starting to use the new pump. If you would like to find out more about these side effect, please ask your doctor, your parent or person taking care of you, as they will have the full list of these.

You should tell your mum, dad, or the person taking care of you, or another grown-up (like a teacher), and the study doctor right away if you feel unwell.

You should **not take any Paracetamol** without telling your mum, dad, or the person taking care of you. It can change the way the study pump works.

WILL BEING IN THE STUDY HELP ME?

You might feel that you have less highs and lows, or you may not. We will help you throughout the study to try to keep you blood sugars as stable as possible.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the study doctors, nurses and other study staff will record information about you and your health. You will not be able to take part in this study if you do not want your information to be collected.

Is my data confidential?

Beside you, your parent(s) or guardian, the doctors/nurses you usually see in your diabetes clinics and other people required by law to make sure this study and devices like the one in this study are safe, the researchers are the only ones who will know the details of you, such as your name, date of birth, and address.

If we publish reports or give talks about this research, we will only discuss group results. We will not use your name or any other personal information that would identify you.

All information about you that will be sent to others (for example, the manufacturer of the study devices) will be marked with a code, but not your name or any of your personal information that could identify you.

WHAT HAPPENS AFTER THE STUDY ENDS?

After the study, you will continue to be supported to by your usual diabetes clinic.

WHAT IF I HAVE MORE QUESTIONS?

You can ask your mum, dad, or the person caring for you, or the study team any questions or tell them about any concerns you have at any time during the study. If you wish, you can also directly contact one of the study doctors: Professor Ben Wheeler, and his phone number is 027 470 1980, or Associate Professor Ryan Paul, his phone number is 021 310 974. You can call them if you have any questions.

Assent Form (for older children)

Study title: ACCESS-AID Study – Accelerating Care, Capacity and Equity in AID Systems for New Zealanders with Type 1 diabetes

Locality: Health New Zealand Ethics committee ref: 2025 FULL 22346

Study sponsor: University of Otago, Dunedin

Lead investigators: Prof Ben Wheeler & Assoc Prof Ryan Paul Contact: 027 470 1980

Participant's name: _____
(Full name filled in by study staff)

Date of birth: _____
(Filled in by study staff)

Please circle all you agree with:

Have you read this form (or had it read to you)?	Yes
Has a member of the study team explained this study to you?	Yes
Do you understand what this study is about?	Yes
Have you asked all the questions you want?	Yes
Do you want to take part in this research study?	Yes

If you **don't** want to take part, **don't** sign your name!

If you **do** want to take part in this study, please write your name, date of birth, today's date, and signature (if you have one) below.

Declaration by participant:

I agree to take part in this study.

Name (and signature): _____

Participant's date of birth: _____

Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____

Date: _____