Participant Information Sheet

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 number: 027 470 1980

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

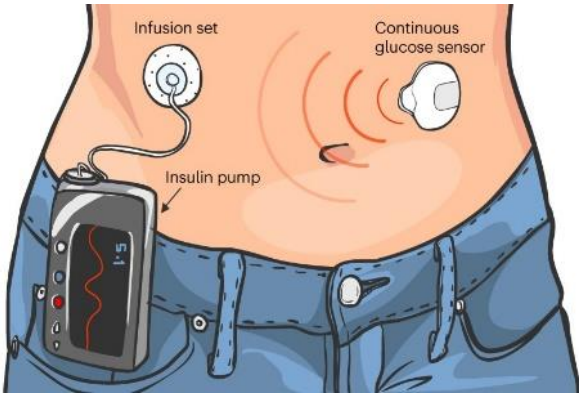
You are invited to take part in this study on a new model of health delivery which is being conducted in partnership with Health New Zealand, Te Whatu Ora. The requirements of this study are explained further in this information sheet.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation involves, what the benefits and risks to you might be, and what happens after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this. If you agree to take part in this study, you will be asked to sign and date the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 14 pages long, including the Consent Forms. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Whether or not you take part in this study is your choice. There is no cost to you for participating in this study. If you don't want to take part, you don't have to give a reason, and it won't affect future care you receive or the relationship with your health care specialist. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

What is the purpose of the study?



Automated insulin delivery (AID) is the recognised best treatment for managing glucose in people with Type 1 Diabetes (T1D) and has been shown to greatly improve glucose outcomes. These systems link a pump, glucose sensor and computer algorithm to automate insulin delivery. The systems continuously adjusts insulin to help keep your glucose more stable.

Despite this, access to these technologies is slow and not always available to those who need them most. Now that this technology is fully funded for people living with T1D in Aotearoa New Zealand, an estimated 10,000 people are expected to want to transition on to insulin pumps in the next year. However, no way near this number are currently being

given access to insulin pumps each year in NZ.

The purpose of this study is to provide a remote 'Hub', as a new model for health delivery, to assist the healthcare system successfully transition individuals with T1D using injections onto AID. We anticipate this will allow individuals in regions struggling with staffing to allow pump starts earlier access to pumps than they would normally receive.

HOW IS THE STUDY DESIGNED?

Anyone living in Aotearoa New Zealand who has been diagnosed with T1D or another condition that meets the PHARMAC criteria for an insulin pump (e.g., Type 3c diabetes), will be able to take part in the study. You do not need to have any experience using an insulin pump or glucose sensor. We will make sure that the health care providers you usually see for your diabetes, are able to continue your care after enrolment in our study.

You will be in this study for up to 3-months. This includes one online telehealth consult with health staff from our Hub and one in-person visit to be trained and started on your new insulin pump. Study staff will touch base with you regularly after you have started on the insulin pump. Generally by 3-months you will be transferred back to your usual diabetes care team for ongoing diabetes related care (some people will be able to transfer back sooner).

The study team will still be able to access your insulin pump and CGM data for another 3-months, so we can review your data at 6-months post starting AID. You will not need to do anything at this point. After this, your data will be removed from the study diabetes management accounts. If you become unwell, or the study doctor is concerned about any of your assessments, you may be asked to schedule extra visits. What exactly happens during the study visits is explained below. All procedures described here will be carried out by trained members of the study team.

Study enrolment

Before any tests are done, you can ask the study team any questions you have about the study, and your consent will be collected. All blood tests completed during this study are routinely collected in usual care for people with diabetes and will be completed by usual Te Whatu Ora/Health NZ affiliated laboratories (rather than research laboratories). We will ask you to visit your local laboratory to have your HbA1c measured. If you have not had a Diabetes Health Screen completed as part of usual care, in the past 12-months we will also measure your blood lipids and renal function and ask you to complete a urine sample to measure albumin:creatinine ratio. These are standard clinical tests not research funded, so tissue disposal will be completed as per laboratory standard protocols which may mean a karakia is not available at time of disposal. If already using a continuous glucose monitor, we will collect 2 weeks glucose data. If you are not already, study staff will support you to begin using a continuous glucose monitor. You will also be asked to complete three questionnaires about your diabetes, and a carbohydrate counting assessment, online or over the phone.

Depending on the result of your carbohydrate counting assessment, you may be invited to attend an online carbohydrate counting/awareness education session, either in a group or one-on-one setting, facilitated by a Registered Dietitian. Attendance at the session is optional, and will not delay access to starting your new insulin pump.

Telehealth consult

You will be asked to attend an online or phone consultation with our study staff. You may ask whānau/support people to attend with you. During this visit you will discuss insulin pump options and have the opportunity to ask any questions about transitioning to an insulin pump. Following this session, you will be asked to decide what insulin pump you would like to start, and the Hub staff will

organize prescriptions for all the equipment you will need.

Pump Start

You will be asked to attend an in-person training session to learn about and start your insulin pump within 1 to 6 weeks after your telehealth consultation. This session may a one-on-one, or a group training session. The training session will be provided by the provider of each insulin pump at a location ideally within 60 minutes from your home address. If you are willing to travel, you may be assigned a training session further than 60 minutes from your home address to speed up your access if you are willing. If this is the case, we will arrange some help to cover the additional travel costs. A virtual pump start may be available if required.

Follow up

You will receive a phone call/text/email from a member of our study staff over the next 3-months to review your insulin pump data. This will happen daily for the first three days, twice weekly for the first week, weekly for three weeks and then monthly ending at week 3-months. Based on your responses to the online carbohydrate counting tool, you may be invited to an online group session of individual consultation with the study Dietitian, to support the nutrition requirements when using AID.

Visit table:

	Enrolment in Study	**Telehealth Consult**	**Start AID (Day 0)**	**3 months**
	Visit 1 (virtual)	Visit 2 (virtual)	Visit 3 (in-person)	Visit 4 (virtual)
Informed consent	X			
Blood test [a] (HbA1c)	X			X
Glycaemic metrics	X			X
Questionnaires	X			X
Carb counting assessment	X			
Insulin Pump Selection		X		
Start CGM (if not already using)		X		
Pump training			X	
Clinical staff support [b]		X	X	X
Dietitian support		X	X	X
Qualitative interview				X

[a] If you have not had a Diabetes Health Screen in the past 12-months we will also measure your blood lipids and renal function and ask you to complete a urine sample to measure albumin:creatinine ratio

[b] A member of the clinical team will be in contact daily for the first three days, twice weekly for the first week, weekly for three weeks and then monthly ending at week 3-months.

3-months

At three months, we will ask you to go to the nearest Te Whatu Ora/Health NZ affiliated laboratory to have your HbA1c measured. You will then be transferred back to your usual diabetes care team for ongoing diabetes related care. We will transfer all of your CGM and insulin pump data, collected during the study to your usual care team.

6-months

At six months, the study team will access your CGM and insulin pump data from the study diabetes data management accounts (Glooko™ or T:Source™). You will not need to do anything at this time point. After the data has been reviewed by the study team, you will be removed from the study diabetes data management accounts, and study staff will no longer have access to this data.

QUALITATIVE INTERVIEW – OPTIONAL SUB-STUDY

We are interested in learning what you think about the process of starting an insulin pump via our remote Hub. Some participants (and their families) will be invited to be interviewed about their experiences with this form of pump training and support. Taking part in these interviews is voluntary. If you agree to take part in this optional sub-study, you may be asked questions about your experiences. This one-to-one interview with a trained member of the study team will occur within four months of starting an insulin pump. The interview will take place over Zoom in a password-protected private meeting. The interview will last approximately 30 to 60 minutes and will be digitally recorded. We will later write the recorded interview out in full and look for similarities and differences between your responses and other participants' responses. If you wish, you can read the transcript of your interview before it is used for the study. Some information collected about you at the start of the main study (age, gender, ethnicity, HbA1c, duration of diabetes) will be used to help describe participants in this optional sub-study. Participants will receive a $50 gift voucher after the interview.

WHO CAN TAKE PART IN THE STUDY?

You have been invited to take part in this study because:

- You have had type 1 diabetes or another condition that meets the PHARMAC criteria for access to an insulin pump (e.g., Type 3c diabetes).
- You have a usual care team who you will return to see for diabetes related care.

If you are currently pregnant, you will not be eligible to participate (we will advise you of the best services for you). Members of the research team will check that you are eligible to take part in the study. Before any screening procedures are done, you will be given a chance to ask any questions you may have regarding the study, and you will sign and date this consent form.

Once enrolled in the study, you will be asked to get a blood test done. If you do not want any of the tests done, you should not take part in this study. Study staff will also contact your GP and/or diabetes specialist about your study participation. We may need to discuss health issues or parts of your medical history that could affect you taking part in the study.

During the study, tests may give an unexpected result that could be important in terms of your health. If this happens, these results will be discussed with you and your GP/diabetes specialist, and appropriate follow-up will be arranged through your usual doctor.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

We are using fully PHARMAC funded systems that are commercially available in New Zealand (i.e. not experimental). Therefore, there are no additional risks as compared to getting an insulin pump through standard care. However, once started on AID, the system may take some time to get used to. We will give you training and support throughout the study, including direct phone access to our study staff in case you need it during work hours, and technical support via the pump suppliers 24/7.

As all insulin pumps have risks that come with using them, the standard risks are outlined below:

Risks related to insulin pump infusion sets currently funded in New Zealand:

General risks related to insulin pump infusion sets may include:

- Skin irritation or redness, bruising, discomfort or pain, irritation, rash (very common)
- Bleeding (common)
- Localized infection (uncommon)
- Blockages that can prevent insulin delivery and lead to high glucose or diabetic ketoacidosis (uncommon)

Diabetic ketoacidosis happens when there is not enough insulin the body cannot use sugar (glucose) as a fuel source. Therefore, fat is used for fuel instead. When fat breaks down, it produces ketones and those can build up in the body.

Risks related to insulin administration and pump use:

Due to the use of insulin, there is risk related to the infusion of insulin and the potential interruptions of insulin delivery (these are the same for injections or pumps). These general risks may include:

- Hypoglycaemia, hyperglycaemia (very common)
- Diabetic ketoacidosis (uncommon)
- Seizure (rare)
- Coma, death (very rare)

You may not have worn a glucose sensor. Risks related to sensors currently funded in New Zealand:

- Skin irritation or other reactions, redness or rash, residual redness associated with adhesive or tape or both, discomfort, pain, soreness, raised bump, appearance of small ‘freckle-like’ dot where needle was inserted (very common)
- Bruising or bleeding, swelling at insertion site, minor scarring (common)
- Infection, sensor breakage or damage, fainting secondary to anxiety or fear of needle insertion, minimal blood splatter associated with sensor needle removal (uncommon)
- Severe allergic reaction (very rare)

Are there any other risks?

Although unlikely, the new model of care we are using to help support you onto pump therapy may cause risks that are not yet known. If any new information is discovered that might affect your decision to continue with the study, you will be told by a member of the study team.

Please tell the study doctor or study staff if you feel unwell at any time during the study (whether you think it is related to the study or not). You will be monitored throughout the study in order to minimize risks.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

This study may have the potential to help you access a pump much faster than from your usual health

care provider. Pumps may reduce your daily diabetes management burden and improve your glucose control and health outcomes. You may also learn more about how different diabetes technology works, and about your own management of your blood glucose levels. Information from this study will be used to further develop how we train people in New Zealand and worldwide onto pump systems.

If you decide not to be in this study, there is other care available to you, as you already receive with your health care professional team. You will continue your current treatments and management with that team. You should discuss other treatments and their benefits with your doctor.

WILL ANY COSTS BE REIMBURSED?

All visits will be conducted virtually/online, with the exception of the pump start in-person training sessions which will be conducted at a location usually within 60 minutes of your home. If you live outside this area, we will discuss your travel costs individually. You will receive a $30 voucher after confirmation of your pump start, and an additional $30 voucher at the end of the study to recognize your contribution and to cover other costs associated with participation, such as travel to the local medical laboratory.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

DATA LINKING - OPTIONAL

Data Linking

In this study we would like to link your study information with other data sets which include information about you. This is called 'data-linking'.

Data-linking in this study is optional.

We would like to link past information with new information collected in the future. Information used to link this data will include your NHI number.

In this study we would like to link to your data in National Collections including:

- Pharmaceutical Collection (PHARMS). Which includes information of dispensing of publicly funded prescription pharmaceuticals and associated equipment including diabetes-related drugs, CGM sensors, insulin pumps and consumables;
- National Minimum Dataset. Which includes information on hospital admissions with coded reasons and procedures received;
- Mortality Collection, will includes information on all community and hospital deaths;
- Virtual Diabetes Register (VDR), which provides information on the estimated prevalence of diabetes in New Zealand.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the study doctors, nurses and other study staff will record information about you, your health and your participation in the study. If needed, information from your hospital records and your GP may also be collected. You will not be able to take part in this study if you do not consent to the collection of this information about you.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

- Study staff (to complete study assessments)
- Your usual doctor and hospital medical teams. All your diabetes clinical information will be transferred back to your usual care team at the end of the study. This allows appropriate follow-up to be arranged.
- Laboratory staff, to process and report your screening tests.
- Representatives from ethics committees or government agencies from New Zealand, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any research related report that will leave the study site (see clinical transfer of care above). For data included in research report, you will be identified by a code. Only study staff will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

- Regulatory or other governmental agencies worldwide.
- The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.
- A description of this study will be available on the public clinical trial registry http://www.anzctr.org.au/. This website will not include any information (identified or de-identified) that can identify you. At most, it will include a summary of the study results. You can search this website at any time.

Security and Storage of Your Information

Your identifiable information is held at secure servers of the University of Otago during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years then destroyed. Glucose information collected by the insulin pump and CGM will be uploaded and stored by Glooko™ or T:source™. These are the same platforms your data will continue to be visible from for all your future diabetes health visits at the GP or hospital. All storage will comply with local and international data security guidelines. Linked data in this study will be destroyed after 10 years.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. Please ask if you would like to access the results of your screening during the study. If you have any questions about the collection and use of information about you, you should ask the study doctor.

Qualitative Interview Data

If you agree to participate in the qualitative interview, the interview recording will be stored on secure servers of the University of Otago. Video and audio recordings will subsequently be transcribed by designated staff. Transcriptions will be coded (de-identified) and original recordings (video and audio) will be deleted.

Use of Glooko™ or T:source™.

Glooko™ and T:source™ are internet-based software systems which allows the device data to be viewed and easily evaluated by yourself and the research team. You will be asked to download the relevant mobile applications (Glooko™ and T:connect™) or use your personal computer to access these systems via the Internet, to upload data from the insulin pump and CGM. The data contained in Glooko™ and T:source™ is accessible using a standard browser, i.e., Microsoft® Internet Explorer, on an Internet enabled PC, or via the Glooko™ and T:connect™ mobile applications. The information available from the Glooko™ and T:source™ Website is the same information the study team would collect from your device during an in-person office visit.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Personal information will be managed in accordance with the New Zealand Privacy Act 2020, Health Information Privacy Code 2020 and other relevant legislation. Even with coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information. Glucose management data uploaded to Glooko™ or T:source™ may be held on servers outside of New Zealand. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

Data-linking can produce a detailed picture of individuals. Data-linking increases the risk of identifying individuals and possibly others who may be in the same households, organisations, iwi or hapū. Some of the data sets being linked may have been designed, and some data may have been collected, without the intention of them being used with other data sets. Some data sets may have been collected in ways which have resulted in biases, meaning that there is the potential for inappropriate inferences to be drawn. These things have the potential to cause harm. While we have taken steps to minimise their likelihood, we cannot guarantee they will not occur.

Confidentiality

There is a risk of loss of confidentiality of your information. This study uses several applications, including the Glooko™ and T:connect™ mobile applications and various other mobile application relevant to available insulin pumps and CGMs. All applications used in this study are commercially available and used in usual care of individuals with T1D using an insulin pump. Thus the risk of loss of confidentiality is not specific to this study as there is always inherent risk in the use of any software or mobile application available for download over the internet or app-store. However, it is still important that you understand what data each device and app collect and how data moves between the apps. Study staff will help you set up accounts for the required apps. This account will be connected to the Glooko™ or T:source™ clinical management account that study staff will have created for you to share your insulin pump system data with study staff. Each app will have terms and conditions that you will need to read and agree to. In addition to those terms and conditions, you agree that the site and the device manufacturer may use the data collected by the apps during the study. The data will include blood glucose data/trends and device alerts, alarms and notifications.

The device manufacturers take reasonable steps to protect the privacy of the health and personal information shared over the internet. However, they cannot guarantee the health information is protected against unauthorized, unlawful interception. Please note there are inherent risks in the use of any software or mobile app available for download on the Internet or from a mobile app store, and there is no guarantee that an internet transmission is 100% secure or error-free. While the Terms of

Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant

WHAT HAPPENS IF I CHANGE MY MIND?

You are free to withdraw from this study at any time without having to give a reason. Information collected up until your withdrawal will continue to be used and the results of these assessments will be included in the study. This is to protect the quality of the study, and to make sure the safety of the new method of insulin delivery is accurately assessed. If you do not wish your information to be used if you withdraw, you should not take part in this study.

You may also be withdrawn from the study even if you want to continue, for example if investigators believe it is in your best interest for you to stop taking part. If this happens you will be told, and the reasons will be explained to you.

If you wish to leave the study early, tell a member of the study staff. You will be asked questions about your experience while you were in the study. Please note if you wish to leave the study early, after starting an insulin pump, the clinical team will continue to provide medical support to ensure your safety, until transfer back to your usual care team can be arranged.

WHAT HAPPENS AFTER THE STUDY?

At the end of the study you will be referred back to your usual health care provider for ongoing diabetes related support. You will be able to keep using the insulin pump, CGM and peripherals provided as all of these will have been prescribed in partnership with the national health system. All items are funded in New Zealand.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You can request a letter telling you about the results of this study. The letter will be sent to you once the final study report is available (this can take 1 – 3 years).

WHO IS FUNDING THE STUDY?

This study is an investigator initiated study funded by The Health Research Council of New Zealand. Dr Wheeler and Dr Paul are in charge of overseeing and running the trial.

WHO HAS APPROVED THE STUDY?

The ethical aspects of this study have been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

You can ask the study team any questions or tell them about any concerns you may have at any time during the study. If you wish, you can also directly contact the study doctor:

Professor Ben Wheeler

Email: ben.wheeler@otago.ac.nz Phone: 027 470 1980

Associate Professor Ryan Paul

Email: ryan.paul@waikato.otago.ac.nz Phone: 021 310 974

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

To ensure ongoing cultural safety, Health NZ – Southern encourage those who identify as Māori, and who are participating in health research or clinical trials, to seek cultural support and advice from their own Kaumātua or Kuia in the first instance, or please contact:

Wendi Raumati & Eleanor Russell, Kaiāwhina

Te Ara Hauora – Māori Health Unit

Dunedin Hospital

Phone: 03 474 0999 ext 58649

Email: kaiawhina@southerndhb.govt.nz

Andrea Jerry, Kaiāwhina

Te Huinga Tahi – Māori Health Cultural Support

Southland Hospital

Phone: 03 218 1949 ext 48509

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Web: https://ethics.health.govt.nz/

Email: hdecs@health.govt.nz

Consent Form

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	
Local investigator:	Prof Ben Wheeler	Contact number: 027 470 1980

Please tick to indicate you consent to the following

I have read and I understand the Participant Information Sheet.	Yes ☐
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.	Yes ☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐
I consent to my information being sent overseas	Yes ☐
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐
I agree that my current health care provider will be informed about my participation in the study and of any significant abnormal results obtained during the study, and that my health care provider may disclose relevant health information to the study doctor.	Yes ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	Yes ☐

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		Yes ☐
I understand the compensation provisions in case of injury during the study.		Yes ☐
I know who to contact if I have any questions about the study in general.		Yes ☐
I understand my responsibilities as a study participant.		Yes ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐
I consent to being contacted about participation in future diabetes research.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: 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:

Consent Form For Participation in the Qualitative Interview

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	
Local investigator:	Prof Ben Wheeler	Contact number: 027 470 1980

Please tick to indicate you consent to the following

I agree to take part in the **optional** interview sub-study about my experiences with the advanced insulin delivery system and remote hub	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in the sub-study of this research study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the sub-study of this research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the sub-study and has given informed consent to participate.

Researcher's name:

Signature: Date:

Consent Form For Participation in the Data-Linking

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	
Local investigator:	Prof Ben Wheeler	Contact number: 027 470 1980

Please tick to indicate you consent to the following

I agree to allow data-linking which **is optional** for this study, whereby data collected about me during this study, to be linked with other data sets which include information about me.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in the sub-study of this research study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the sub-study of this research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the sub-study and has given informed consent to participate.

Researcher's name:

Signature: Date: