ADULT INFORMATION SHEET

Evaluation of the DS5 performance over a fifteen-day wear period

Why are we doing the study?
We are trialling a new continuous glucose monitoring (CGM) sensor called Disposable Sensor 5. We want to see how the sensor performs over a 15-day period. The Disposable Sensor 5 is not yet approved for sale in Australia.

This is a combined Perth Children's Hospital and Telethon Kids Institute's investigator-led study conducted in Perth Children's Hospital with investigational devices and grant funding from Medtronic USA.

Why are we asking you?
We are asking you to take part in this study because you have Type 1 diabetes; and are aged between 18 to 26 years old.

Who is carrying out the study?
The study is being carried out by **Professor Timothy Jones** and **Dr Mary Abraham** of the Department of Endocrinology and Diabetes at Perth Children's Hospital (PCH) and the Children's Diabetes Centre, Telethon Kids Institute.

What will the study tell us?
This study will tell us how the sensors perform during a hypo (low blood glucose level) or hyper (high blood glucose level) event, which will be induced under controlled conditions at PCH. It will also tell us how these sensors perform when you continue to do what you usually do day to day, over the fifteen-day study period.

Do you have to take part?
No, you do not have to take part in this study. Participation in this study is entirely voluntary. If you decide to take part and then later change your mind, that is ok. You can withdraw from the study at any time and it will not change the way you are treated by your clinic team.

What will you be asked to do if you decide to take part in this study?
If you take part in this study, we will ask you to wear two to four sensors on your arms for fifteen days. The sensors are inserted under your skin so that they can continuously track your blood glucose levels. This combined sensor-transmitter CGM device provides a reading every five minutes, and the sensor is coated with dexamethasone (steroid) which is meant to make the sensor last longer than the usual seven-days. For this study, you will need to attend Clinic D at PCH on three to four separate days, depending on your induction days.

On **Day 1** (2 hours) when you attend Clinic D in PCH, we will**:**

- Go over the study with you
- Show you how the DS5 works
- Ask you to sign the study consent forms
- Give you an appointment schedule
- Insert two to four sensors
- Give you the following instructions to follow at hom
    - Testing your blood glucose levels at least 6 times a day, using the study blood glucose meter
    - Continue with your usual diabetes management
    - Keep a record of your activity, medication, and diabetes management in the fifteen days you are wearing the sensors.
- For most participants this day is separate from the hypo/hyper induction days.
    - Four will have the hypo induction within 24h of the sensor insertions
    - Four will have the hyper inductions within 24h of the sensor insertions

Two Induction Days (6 hours) **within the fifteen-day Period**:
For the induction days – you will need to fast from midnight for this study. But if you have a hypo, you will treat the hypo like you would usually do. The study will still proceed as planned. Please note that you should not have any extra insulin after 4am in the morning on induction days. We will put a drip in one of your arms (usually in the crease of the elbow). We will then use this drip to take 0.2 mL of blood every 15 minutes for the rest of the study, to measure your blood glucose levels. However, when your blood glucose level is <4 mmol/L or >13.9 mmol/L we will test your blood glucose levels every 5 minutes. Finger pricks will also be taken at the same time. In total, up to 18ml of blood will be gradually collected per induction day.

- **HYPO INDUCTION**
  During this 4-6 hours induction, we will lower your blood glucose level to 3 mmol/L. This will be done by giving you an insulin bolus, based on your insulin sensitivity factor. Once your blood glucose level is <4.1 mmol/L (but not lower than 2.8 mmol/L) up to 120 mins, we will then give you your usual hypo treatment to bring it back up to 5 mmol/L. However, if you are unable to tolerate the hypo symptoms, we will give you your usual hypo treatment immediately to bring it back up to between 5-6 mmol/L.

- **HYPER INDUCTION**
  You will be given a breakfast with enough carbohydrates to increase your blood glucose level to >13.9 mmol/L. You will not take an insulin bolus for the meal. Once you are >13.9 mmol/L up to 120 mins, we will then ask you to take an insulin bolus to bring your BGL to between 5-6 mmol/L.

Non-Clinic Testing Days within the Fifteen-day Period: This part of the study is called the free-living period and you do not have to come into PCH. During this period, you will:
- Continue with your usual daily activities
- Test your blood glucose levels at least 6 times a day on the study meter
- Continue with your usual method of managing your diabetes

- If your blood glucose is low (<4.0 mmol/L), check finger prick glucose levels 15 minutely using the study blood glucose meter, as you usually would following hypo treatment, until it is above 4.0 mmol/L

On **Day 15** (1 hour – end of the study) when you return to the Clinic D, we will**:**

- Perform two finger prick glucose levels 15-minute apart to mark the end of the study
- We will remove all of the sensors and thank you for your participation

Throughout the fifteen days, we will ask you to keep a record of your activity, medication, and diabetes management.

You will be reimbursed for parking, travel, and meals when you attend a study visit.

Is there likely to be a benefit to me?
There is likely no benefit to you in participating.

However, sensor accuracy and prolonged sensor life is essential in not only aiding routine diabetes management, but also in its integral role in closed loop technology. Hence, this study will add to the data that will give people with diabetes the confidence in the technological advances in diabetes management.

What are the possible risks and/or side effects?
There is a small risk of bruising, bleeding, infection, or skin reaction at the sensor insertion and/or cannulation site. However, our trained nurses will follow the user guide instructions and the hospital patient care procedures to minimise the risk when inserting the sensors. If there is any adverse reaction, then the sensors will be removed. You may also be unable to tolerate the hypo or hyper symptoms. If that is the case, we will treat them as required to return your blood glucose level to a level which you will find tolerable. Our trained staff and strict protocols will minimise these risks. On the two induction days, you will be constantly supervised and blood glucose levels monitored every 15 minutes.

What are the possible discomforts and/or inconveniences?
You may find wearing the sensors uncomfortable for those who had never used a sensor before. You may also find wearing four sensors uncomfortable; you will thus be given a choice as to the number of sensors that you are willing to wear.

Where is my information kept?
All electronic study information will be coded and stored on restricted access, secured database at PCH and Telethon Kids Institute, and retained for 25 years after study completion. Paper records will be stored in Telethon Kids Institute restricted access cabinet and archived at study completion in an archiving facility for minimum of 15 years after study completion, and destroyed thereafter. The glucometer and CGM de-identified data are also stored permanently in a Medtronic database without your name – this is what happens when sensors data are uploaded onto their database.

The team would also like to keep your data to share with research collaborators both in Australia and overseas in potential future research. This is optional. Any collaborative

research where we might use your data will need to be approved by a Human research Ethics Committee and we will make sure that your identity is protected at all times.

What about my privacy?

Your personal data will only be identified by a unique code, and only the investigators and the research team specific to the study will be able to link the results to you. Publications and presentations about the results of this study will not identify anyone by name. Your involvement in this study will be recorded in the clinic database, and health records.

Who has approved the study?

The Child and Adolescent Health Service Human Research Ethics Committee have approved this study. 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 would like any more information about this study, please contact:

Name: Niru Paramalingam – Diabetes Research Coordinator
Contact no: (08) 6456 4611
Email: **niru.paramalingam@health.wa.gov.au**

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

If you have any concerns or complaints regarding this study, you can contact the following:

Name	CAHS Research Ethics & Governance Office
Position	Manager
Telephone	(08) 6456 8639
Email	CAHS.RGO@health.wa.gov.au

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

If you would like to take part in this study, you can contact Niru on 08 6456 4611, to make an appointment. You will be asked to sign a consent form for participation in this study when you attend your first study appointment.

THANK YOU FOR READING THIS INFORMATION SHEET

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

Perth Children's Hospital

TELETHON KIDS INSTITUTE
Discover. Prevent. Cure.

children's diabetes centre
Research. Education. Advocacy

ADULT PARTICIPANT CONSENT FORM

Project Title: **Evaluation of the DS5 performance over a fifteen-day wear period**

Chief Principal Investigator: Professor Timothy Jones *Consultant Paediatric Endocrinologist, Perth Children's Hospital; Co-Director of the Children's Diabetes Centre, Telethon Kids Institute.*

- ☐ I have read, or have been read to me, the information statement version above and I understand its contents.
- ☐ I believe I understand the purpose, extent, and possible risks of my involvement in this study.
- ☐ I voluntarily consent to taking part in this study and I understand that I may withdraw from the study at any stage and withdrawal will not impact on routine care.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- ☐ I agree that research data gathered from this study may be published, provided that names are not used.
- ☐ I understand that data gathered from this study may be used in future collaborations and studies nationally and/or globally.
- ☐ I understand that this study has been approved by the Child and Adolescent Health Service Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2023).
- ☐ I understand I will receive a copy of this Information Statement and Consent Form.

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Participant's Name	Participant's Signature	Date

Declaration by researcher:
I have supplied an Information Sheet, version listed as above, and Consent Form to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

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Researcher's Name	Researcher's Signature	Date