ADOLESCENT 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 at 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 14 and less than 18 years old.

Who is carrying out the study?
The study is being carried out by **Professor Tim 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 decided to take part and then later change your mind that is ok. You can withdraw 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 the Research Unit at PCH on three to four separate days, depending on your induction days.

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

- Go over the study with you and your parent
- Show you and your parent how the sensor works - if you have never used a sensor before
- Ask you and your parent to sign the study consent forms
- Give you and your parent an appointment schedule
- Insert two to four sensors
- Give you the following instructions to follow at home:
  - Testing your blood glucose levels at least 6 times a day, using the study blood glucose meter
  - Continue with your usual management practice
  - 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 blood glucose levels at least 6 times a day

- Calibrate the sensors once a day
- 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 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 and/or your parent 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 participating in this study.
However, sensor accuracy, and a longer sensor life, is important in routine diabetes management, and 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 you 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 softcopy of 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.

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 your results to you and your parent. 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 and/or your parent have any concerns or complaints regarding this study, you and/or your parent 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 and your parent 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