Participant Information Sheet/Consent Form

Health/Social Science Research - *Adult providing own consent*
University of Melbourne

Title	The Flash Study Evaluation: Evaluating the barriers, enablers and processes of using continuous glucose monitors for Aboriginal and Torres Strait Islander people with type 2 diabetes
Short Title	Flash Study Evaluation
Protocol Number	1.4
Project Sponsor	University of Melbourne
Coordinating Principal Investigator/ Principal Investigator	Prof Elif Ekinci
Associate Investigator(s)	Flash Study Evaluation Team Members; Mariam Hachem, Leonid Churilov, Marlena Klaic, Sandra Eades, Tracey Hearn, Raymond Kelly, Hannah Morris, Belinda Moore, Zoe Williams, David O'Neal, Luke Burchill, Digsu Koye, Gerrard Rayman and Flash Study Investigators.
Location	Australia

What does my participation involve?

You are invited to take part in this research project, which is called **The Flash Study Evaluation**. You have been invited because you are a healthcare professional/team member involved with the Flash Study. This document explains the research project and processes involved to help you make an informed decision about participation. Participation is voluntary. If you decide to take part and later change your mind, you are free to withdraw at any time.

Aims: To improve the health and wellbeing of Aboriginal and Torres Strait Islander people by generating evidence that will support the effective implementation of digital innovations such as continuous glucose monitoring to supplement face-to-face care.

Research Question:

- What are the barriers and enablers to using continuous glucose monitoring within the Flash Study?
- What are some pathways to overcome these barriers?

Expected Outcomes: To identify the barriers and enablers of using continuous glucose monitoring across health services in urban, regional, rural, and remote Australian health settings.

All data will be deidentified and anonymous.

You will be asked to participate in a semi-structured interview with Marlena Klaic, one of the researchers in this study alongside Mariam Hachem and supporting study team members listed on the project.

Marlena (and/or Mariam or another team member) will explore your experience of being involved in a clinical trial using diabetes technology, your experiences, barriers and enablers.

The interview will take up to 45 minutes and will be conducted at a time/day and venue of your selection, including online if this is preferred.

The interview will be audio-recorded and later transcribed by an automated online service (https://www.rev.com/) which has strict confidentiality agreements. If you prefer not to be audio-recorded, we can still undertake the interview and will take detailed notes. All data will be confidential and you will be anonymous (coded ie. P1, P2 for participant 1, participant 2).

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St. Vincent's Hospital Melbourne. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Up to 30 people taking part in this project. It has been designed in collaboration with a range of health professionals experienced in research and clinical practice, and included input from teams using continuous glucose monitors. This project is being overseen by Prof Elif Ekinci.

Do I have to take part in this research project?

NO. Participant is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the Study team (University of Melbourne).

What are the possible benefits of taking part?

There will be no immediate benefit to you from your participation in this research. However, your involvement will help us to better understand the barriers and enablers of using continuous glucose monitoring in a real-world setting. **You will be provided a voucher for $50 for participating in the interviews.**

What are the possible risks and disadvantages of taking part?

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

What if I withdraw from this research project?

You can withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

After your involvement in the research project is completed, you will not need to attend any further interviews. The results from the project will be published in relevant health journals and presented at relevant conferences. You will be offered a one-page summary of the overall research findings once the study is completed.

Who is organising and funding the research?

This funded research project is being supported by the 2022 MRFF Assessment of High-Cost Gene Treatments and Digital Health Interventions Medical Research Future Fund Grant (Application ID: 2025170) led Prof. Elif Ekinci. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than ordinary wages). The results from this study will contribute to higher degrees for team members (Mariam Hachem, Coralie Cross and/or other team members enrolled in a higher degree).

Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact Prof Elif Ekinci or Mariam Hachem via email; elif.ekinci@unimelb.edu.au or mariam.hachem@unimelb.edu.au or any of the following people:

Research contact person

Name	Mariam Hachem
Position	Project Manager
Email	*mariam.hachem@unimelb.edu.au*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	
Position	
Telephone	
Email	

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	**St. Vincent's Hospital Melbourne HREC**
HREC Executive Officer	**HREC Executive Officer**
Telephone	**(03) 9231 6970**
Email	**Research.ethics@svhm.org.au**

Local HREC Office contact

Name	
Position	
Telephone	
Email	

Consent Form - *Adult providing own consent*

Title	FlashGM Study Evaluation: Evaluating the barriers, enablers and processes of using continuous glucose monitors for Aboriginal and Torres Strait Islander people with type 2 diabetes
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Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. 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 freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care. I understand that I will be given a signed copy of this document to keep.

I am aware that the interview audio-recording may be provided to a third-party service provider (www.rev.com) for transcription. I acknowledge that information captured in the interview recording will be subject to the terms of service and privacy policy of rev.com and information will be stored and processed by rev.com overseas.

☐ I consent to having the follow-up interview audio recorded

☐ I agree to the interview transcription through a third-party provider

I would like a summary of the results of this study ☐ No ☐ Yes

My preferred method of communication of the results is: ☐ Email ☐ Post

My contact details are: _____

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

* Witness is not to the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

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 _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or the University of Melbourne.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research.

Note: All parties signing the consent section must date their own signature.