Mature Minor Participation Information Sheet

Title	**The mobile food record: A pilot study using images to assess dietary intake in children and adolescents with type 1 diabetes.**
Short Title	mFR in T1D Pilot Study
Protocol Number	RGS0000003855
Coordinating Principal Investigator	Dr Amelia Harray
Location	Telethon Kids Institute

1 Introduction

You are being invited to take part in a study involving children and adolescents who have had type 1 diabetes (T1D) for more than a year and are using a continuous glucose monitor. The aims of this study are to see if:

(1) children and adolescents like using a mobile food record App to take images of what they eat or drink, and

(2) whether the images they take are clear enough for a dietitian to estimate how much they are eating and drinking.

This information sheet tells you about the study and explains what you will be asked to do. Please read this information. Then ask any questions you may have about the study. If you want to take part in this study, you will be asked to give your consent to a member of the research team over the phone or sign and return the Consent Form. The Consent Form is on the final page of this Information Sheet, and tells you what you are agreeing to, when you consent to participate in the study.

2 Why are we doing the research?

Recording what you eat and drink can help a dietitian give them specific and tailored dietary advice. However, keeping written food records can be time consuming and challenging for people. Using technology allows users to take images of what they are eating and drinking, which are then automatically uploaded and reviewed by a dietitian. This study is looking to see if children and adolescents can use this mobile App without the help of others.

3 What will the study involve?

The study involves you taking images of all they eat and drink for four days in a row, using an App designed by the investigators, known as the mobile food record (mFR) App. We ask that you wear your continuous glucose monitor over this four-day period and upload your CGM trace at the end of the study, just like you do before going to clinic. Your traces will only be used by the study team for the purposes of this study.

Once you have agreed to participate, you will be emailed a link to download the mFR App, which contains video instructions on how to take 'before' and 'after' images using the App. You will also be emailed surveys for you to complete online (with your assistance if needed), before and after using the mFR App.

You will be mailed a small *checkerboard marker,* which is a colourful square about the size of a credit card to be included in all the images. This marker will help a dietitian work out the portion sizes of food and drinks in the images.

Your age, gender, diabetes duration, most recent HbA1c and BMI z-score will be accessed to work out how your dietary intake compares to national nutrition recommendations.

4 What will you be asked to do if you choose to take part in the research?

You will not have to attend Telethon Kids Institute or Perth Children's Hospital to complete this study. All communication and surveys will be done via the telephone, internet, and email.

During the study period you will be asked to take 'before' and 'after' images of everything they eat and drink, and to wear your continuous glucose monitor, and calibrate it twice a day. There are no changes to what you normally eat and drink, or to your insulin regime. These images get automatically uploaded to a secure password protected online server that only the research team can access and do not contain any personal information about you.

Before and after the four-day study period, you will be asked to complete online survey. Each survey will take 10-15 minutes to complete.

5 Who is carrying out the research?

Researchers from the Children's Diabetes Centre at Telethon Kids Institute are working together with Researchers from Curtin University to conduct this research. Funding for the research has been provided by the Children's Diabetes Centre.

6 Do you have to take part in this research?

You do not have to take part in this study. If you decide to take part in the study, but then change your mind, you are free to pull out of the study at any time. Please let us know if you no longer want to be part of the study – this will not affect how you are looked after by the diabetes team at Perth Children's Hospital.

7 Is there likely to be a benefit to me?

We cannot promise that you will benefit from being part of the research. However, you will receive feedback about your current food intake and how these compare to food recommendations for good health.

8 What are the possible risks or side effects?

There are no risks to you in taking part in this study. The study requires that you take images of what they eat and drink. No changes will be made to your diabetes management by the research team, and your diabetes treatment will continue to be managed by your clinical team.

High glucose levels and hypos sometimes happen with diabetes and they may happen during the research period. For hypoglycaemia (blood glucose level <4mmol/L) treat by giving 5-15g of fast acting carbohydrate immediately and check glucose levels in 15 to 30 minutes. For hyperglycaemia (blood glucose level >15mmol/L), please test for ketones and treat with insulin if ketone levels are >1mmol/L. Please see the link below for hypoglycaemia and hypoglycaemia management
https://diabetes.telethonkids.org.au/siteassets/media-docs---childrens-diabetes-centre/sickday.hypo.hypermanagement.pdf.

9 What will happen to your information?

Any information about you that is collected as part of this research will be kept private. Electronic data will be password-protected and hard copy data will be stored in a locked cupboard or on a computer that only the research team can access. However, the continuous glucose monitoring, which is a part of your usual diabetes management, will be accessible by the clinical team. The study information will only be used for this research project.

You have the right to ask to see the information that has been collected about you as part of this research. If you want any of the information to be shared with your clinician, please inform the researcher.

At the completion of the study, potentially identifiable files will be kept for at least fifteen years. All data will then be destroyed in keeping with the Department of Health Patient Information Retention and Disposal Schedule.

The results of this research may be presented at conferences or published in professional journals. Any information that can identify you will be removed before the results of the study are shared with other people.

10 Who has approved the study?

All research in Australia that involves humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This research project has been approved by the Child and Adolescent Health Service Human Research Ethics Committee. 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.

11 Who to contact if you have any complaints about the project or the way it is being conducted

If you have any concerns about your rights as a participant in the study or you have a complaint about how the research is carried out, you can contact an independent person, the Executive Director Medical Services at Perth Children's Hospital (Telephone No: 6456 2222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

12 Who to contact for more information about this study

If you would like any more information about this study, please do not hesitate to contact a member of the research team. They are very happy to answer your questions.

Contact person for the research team

Name	Dr Amelia Harray
Position	Coordinating Principal Investigator
Telephone	(08) 6456 5882
Email	Amelia.Harray@telethonkids.org.au

Mature Minor Consent Form

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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.

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 health care at PCH.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study 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 _____

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