[insert site logo]

# Participant Information Sheet and Consent Form – Adult providing consent for child

|  |  |
| --- | --- |
| **Title** | Apps and Peer support for a Healthy future and Living Well with Diabetes – Mental Health |
| **Short Title** | APHLID-M |
| **Study ID Number** | (to insert) |
| **Project Sponsor** | Western Sydney University |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor David Simmons |
| **Location** | Diabetes clinics across SWSLHD |

# Part 1 What does the child’s participation involve?

## 1 Introduction

Your child is invited to take part in the Apps and Peer support for a Healthy future and Living Well with Diabetes – Mental Health (APHLID-M) study as they are a young adult with either Type 1 diabetes or Type 2 diabetes who attends clinics in SWSLHD.

This Participant Information Sheet/Consent Form tells you about the research project and explains the processes involved with APHLID-M. Knowing what is involved will help you decide if you want them to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not you want your child to participate, you might want to discuss it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don’t wish your child to take part, you don’t have to. You can decide that they take part in some elements of the research and not others. They will still be able to take part in the study) even if you do not want your data collected. If you decide that they will not take part this will not affect their health care.

## 2 What is the purpose of this research?

The APHLID-M Study has been designed for young adults with diabetes. Managing diabetes can be stressful, and often becomes more demanding when entering adolescence and young adulthood. Young people are expected to start taking responsibility for their own care while coping with the physical, emotional, and social stressors of adolescence, which can impact diabetes self-management and glucose control. The current study will evaluate whether young peoples with diabetes mental health, well-being and physical health will be improved using a digital platform application, which has been shown to facilitate improvements in diabetes self-management.

We are looking to find how best such a program can improve the wellbeing and quality of life of young adults with diabetes.

This research has been initiated by a Distinguished Professor of Medicine, Prof. David Simmons.

## 3 What does participation in this research involve for my child?

Participation in the APHLID study involves them having health assessments which includes:

* Completing questionnaires that will explore a little bit about them (eg their age, gender, educational level) their mental health, their knowledge and understanding of diabetes, their diabetes-related conditions, and their quality of life.
* Health measurements, which includes height and weight. Participation in this study will also involve them donating two blood samples (one at the start and one at the end of the study), so that we can assess their blood sugar level on the day of blood sample collection, their average blood sugar levels over the past 3 months (HbA1c) and their cardiovascular health by measuring the levels of a protein in their blood called adiponectin. Approximately 10mL of blood will be collected from a vein in their forearm in a sterile and safe manner by a Research Nurse or doctor at the clinic. After collection their blood will be sent to the laboratory for analysis.
* Data will be collected at two time points - at the very start of the study and 6 months later, which will mark the end of the study.
* As a participant in this study, they will receive an activity tracker to keep, that we will ask that they wear for the duration of the study to monitor their physical activity levels, sitting time and sleep patterns. Please know that we will not be tracking their location. There are 2 groups in this study: an intervention group, who will receive an App for 6 months and a usual care group, who will not receive the App and continue as they normally would. They will be randomly allocated to one of these groups. Participants who are randomised to the Intervention group will be required to download the App to their phone (Apple or Android) to use throughout the trial. The App contains diabetes resources. Data collected by the App will be deidentified (that is their name will not be associated with the information) and analysed as part of the study. Participants who are not randomised to the Intervention group will be given the opportunity to download the App to their phone at the completion of the study.

Participation also involves:

* Giving your permission for the future linkage of some of their data collected in this study to data collections held by NSW Health to determine whether the program helps improve their glucose control.
* For those in the intervention group, helping us to evaluate the App by completing a short online questionnaire and a sub-group of those in the interventions group participating in a one to one or group discussion with a researcher to gather their feedback.
* It does not cost any money to take part in the project. There is no payment for taking part in the project, however you will get to keep the activity tracker as a thank-you for their participation.

## 4 What does my child have to do?

We would like you to consent for them to:

• attend an appointment at their regular diabetes clinic for a data collection session, where a Research Nurse can help them complete the study questionnaires and collect their health measurements, which will include donating a blood sample for the assessment of adiponectin and HbA1C. The questionnaires will take around 20 minutes to complete and the health measurements (including collecting a blood sample) about 20 minutes. The same information (data) would be collected from them the completion of the study (after 6 months).

We would like you to consider for them:

• For those randomised to the intervention group, attending a one-to-one or group discussion if asked, taking no more than 60 minutes, on the completion of the APHLID study. Discussions will help us gain their feedback on what worked well, any challenges and how the App could be improved. We will ask you if it is ok to voice record the discussion, so that we can type-up discussions for analysis.

• Allowing us to store their blood samples in our secure freezers located at Western Sydney Universityfor use in future studies of diabetes and its risk factors and complications The use of these samples in other studies will be subject to ethics approval and they will be destroyed after 5 years.

## 5 Other relevant information about the research project

The current study is being piloted 10 diabetes centres from NSW and Victoria. Participants in this study will be required to have access to a smart phone.

## 6 Does the child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for them to take part, you do not have to. If you decide for them to take part and later change your mind, you are free to withdraw them from the project at any stage.

If you do decide for them 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 as to whether they take part or not to take part, or to take part and then withdraw, will not affect their routine care, their relationship with those treating them or their relationship with [insert site name].

## 7 What are the possible benefits of my child taking part?

We cannot guarantee or promise that your child will receive any benefits from this research; however, this program will provide participants with a wearable device to keep and will enable them to share their diabetes-related knowledge and experiences. This program may help them better control your diabetes and thereby delay the development of complications.

## 8 What are the possible risks and disadvantages of my child taking part?

Risks associated with your child’s participation are limited to those imposed by blood donation. We will minimise risk with the following measures:

• Each participant’s blood is collected through a new sterile needle that is used once and then discarded.

• It is important for them to tell the nurse or doctor on duty if they are feeling unwell or faint before, during, or after collection.

• Small bruises around the collection site are not uncommon. To avoid larger bruises, we recommend that you follow all instructions given to you by the nurse and that light pressure is kept on the collection site after donation for 2 minutes. Also avoid heavy lifting and strenuous use of your donation arm for 6-8 hours after donation.

• Very occasionally, they may experience bleeding from the needle site – if this happens, they should lift their arm above their shoulders and press on the needle site and seek assistance.

If your child participates in a one on one or group discussion, there in a chance that they may find some of the questions we ask are stressful or upsetting. If this happens, they may pause or decline to answer a question and go to the next question or stop immediately. If they become upset or distressed because of participating 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.

## 8 What if I withdraw the child from this research project?

If you do consent for the child to participate, you may withdraw them at any time. If you decide to withdraw the participant from the project, please notify a member of the research team. If you decide that the participant is to leave the research project, the researchers will not collect additional personal information, 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 of withdrawal will form part of the research project results. If you do not want the participant’s data to be included, you must tell the researchers when withdrawing from the research project.

## 9 What will happen to my test samples?

The study involves the collection of blood samples from their forearm. After the blood sample has been collected the sample will be deidentified and sent to the laboratory for analysis.

## 10 What if I withdraw my child from this research project?

If you do consent to for your child to participate, you may withdraw them at any time. If you decide to withdraw them from the project, please notify a member of the research team. If you decide for them to leave the research project, the researchers will not collect additional personal information from them, 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 your child will form part of the research project results. If you do not want their data to be included, you must tell the researchers when you withdraw them from the research project.

## 11 What happens when the research project ends?

Following completion of the research project, the results will be made available to participants if requested.

# Part 2 How is the research project being conducted?

## 12 What will happen to information about the child?

By signing the consent form, you consent to the research nurse and relevant research staff collecting and using personal information about your child for the research project. Any information obtained in connection with this research project that can identify them will remain confidential. The data will be kept in password protected computers and paper files will be kept in locked file cabinets in a locked room. Paper files will be kept for 5 years. Their personal data (e.g., name, address) will be kept separate from the research data. The participant’s information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law. Information about your child may be obtained from their health records for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to their participation in this research project.

Their health records and any information collected and stored by the study doctor during the research project may be reviewed for the purpose of verifying the procedures and the data. This review may be done by the ethics committee which approved this research project, regulatory authorities, and Western Sydney University, or as required by law. In these circumstances, the Sponsor will not collect (i.e., record) any personal information. By signing the consent form, you authorise release of, or access to, this confidential information as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Any information about your identification will be removed from the results, and only overall results will be presented.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information about your child that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## 13 Compensation

If the child suffers any distress or psychological injury because of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support for them. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

## 14 Who is organising and funding the research?

This research project is being conducted by Distinguished Prof. David Simmons and other investigators in his team. It is being funded by Western Sydney University through an external Targeted Translation Research Accelerator Grant.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

## 15 Who has reviewed the research project?

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 South Western Sydney Local Health District. 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.

## 16 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, you can contact: the study coordinator, Karen Mathews, on (02) 4634 4596 or email aphlid@westernsydney.edu.au.

## 16. Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / email SWSLHD-ethics@health.nsw.gov.au, website: <http://www.swslhd.nsw.gov.au/ethics/default.html> and quote [Local project number]

**Thank you for taking the time to consider this study. If you wish to take part, please sign the attached consent form. This information sheet is for you to keep.**

[insert site logo]

***[insert site name]***

# Apps and Peer support for a Healthy future and Living Well with Diabetes – Mental Health

# Consent Form – Adult Providing Consent for Child

**Declaration by parent/Guardian**

1. I ,................................................................................................................. of

.....................................................................................................................

agree for my child to participate in the study described in the participant information statement attached to this form. By ticking below, I provide my consent for them:

 completing questionnaires and health measurements

 donate a blood sample at baseline and 6 months to test for metabolic markers associated diabetes related complications and cardiovascular related risk

 the storage of their samples by the study group for use in future studies of diabetes and its risk factors and complications

 downloading and using the App if they are in the intervention group

 participating in a discussion about participation in the programme

 having my discussion audio recorded

 having their NSW Health data accessed and analysed

 the linkage of their healthcare data, as described in the relevant section of the Participant

Information Sheet

1. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
2. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm that my child might suffer because of their participation, and I have received satisfactory answers.
3. I understand that my child can withdraw from the study at any time without prejudice to my relationship with the **[insert site name]**.
4. I agree that research data gathered from the results of the study may be published, provided that my child cannot be identified.
5. I understand that if I have any questions relating to my participation in this research, I may contact Dr Karen Mathews on (02) 4634 4596 or Dr Freya MacMillan on (02) 4620 3464, who will be happy to answer them.
6. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Signature of Parent/Guardian Please PRINT name Date**

**[*or person responsible] (insert or delete as necessary*)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of investigator Please PRINT name Date**