Centre for Online Health
FACULTY OF MEDICINE, THE UNIVERSITY OF QUEENSLAND

Participant Information Sheet and Consent Form

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Title	**Mobile-based Disease Management System for insulin dose adjustment in type 2 diabetes for specialist outreach and diabetes telehealth service (REMODEL-IDA)**
Short Title	**mHealth for Insulin Dose Adjustment (REMODEL-IDA)**
Project Sponsor	**Queensland Health**
Principal Investigator	**Dr Anish Menon**
Location	**Princess Alexandra Hospital**
Protocol	**HREC**

* Endocrinologist & PhD Student.

Part I – What does my participation in the study involve?

1 Introduction

You are invited to take part in the research study "Mobile-based Disease Management System for insulin dose adjustment in type 2 diabetes for specialist outreach and diabetes telehealth service (REMODEL-IDA)", which may be suitable for you. Before you decide if you wish to participate we would like you to understand why the study is being done, what it will involve and how your information will be used. Please take the time to read the following information carefully and, if you wish, discuss it with friends, relatives and your local doctor. One of our team will go through the information sheet with you and answer any questions you have. Please ask questions about anything that you do not understand or want to know more about.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in this research project.

2 What is the purpose of this research?

The purpose of this project is to test a new model of care for insulin-dose adjustment for type 2 diabetes patients utilising newer technologies like smartphone, Bluetooth glucose meter and transmission of clinical data to a clinician web-portal.

Currently, insulin dose adjustment is offered to people with diabetes in-between clinic appointments, who are either initiating insulin or for those already on insulin requiring dose adjustments to achieve optimal blood glucose targets. The current insulin dose adjustment process could be more efficient, and potential issues that could be addressed are (1) ineffective communication due to unavailability of a

diabetes educator and the patient simultaneously leading to inefficient time management, (2) lack of readily available patient blood glucose levels data and (3) the possibility of transcription errors using conventional approaches of data recording via the telephone.

This new model explores whether it can improve blood glucose management by improving self-management; improve patient satisfaction; and improve the overall efficiency of the insulin dose adjustment service as compared to current model of care.

3 Why have I been chosen?

We are asking adults with type 2 diabetes who are attending this diabetes clinic to participate in this study. We are asking people who have a smartphone with Internet access, such as Wi-Fi, mobile 3G or 4G Internet.

4 Do I have to take part in the research?

It is up to you to decide whether or not to take part in this study. If you decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep. If you decide to take part you can change your mind later and withdraw from the study at any stage, for any reason. Your decision not to take part, or take part and then withdraw from the study will not affect your routine treatment or future health care.

5 Other relevant information (i.e. size of project, number of participants, organisations)

We need forty-four participants to take part in this study. This study is a joint project by Queensland Health, the CSIRO's Australian e-Health Research Centre, and the University of Queensland.

6 What will happen to me if I take part?

You will be participating in this research study after signing the consent form. You would have been referred to the insulin-dose adjustment service already by your doctor.

Participation in this project involves:

- First you shall be randomly allocated to either the group employing existing model of care or the proposed new model of care for insulin-dose adjustment.
- If you are allocated to the existing model of care, there will be no change to your routine care that you would receive otherwise
- If you are allocated to the group employing the new model of care,
    - You will receive a new glucose meter and will be asked to use this meter to check your blood glucose levels. You will be assisted to download the mobile application on your mobile phone. The application will be set to automatically send the blood glucose readings from the study glucose meter to the study database and allows you to enter the amount of insulin you injected on a particular day. Please note the entries that are uploaded are not monitored daily but on scheduled days of the week that is pre-arranged by the diabetes nurse with you.
    - A member of the research team shall test the transmission of a blood glucose level to the web-portal.
    - You will receive computer generated text messages on your phone, based on your blood glucose management, if you opt to receive one. These messages are intended to provide you with information regarding improving your diabetes management. Please do not reply to these messages as they are not monitored
    - You will receive feedback regarding your insulin-dose adjustment from the diabetes nurse via text-messages on your mobile phone. If there are any concerns, you will be able to contact the diabetes nurse via the telephone.
    - You will be asked to provide feedback regarding using this new model of care.
    - The time taken for entering the dose of insulin on the mobile application is estimated to be about 2 minutes per each injection. Sending the information to the system will take close to no time because it happens automatically
    - At the end of the study you will be required to have an appointment with a member of the research team which could be face to face, online video-conference or over the

phone, whichever is suitable. This appointment is for completion of feedback questionnaires and arranging for pathology tests

- You will have bloods checked at the start of the study, at 4 weeks and at 3 months. The blood tests done are to assess your blood glucose management.
- You will be required to fill in questionnaires as part of the study – at the start of the study, at 4 weeks and at 3 months.
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7 What are the possible benefits of taking part?

This study intends to use the potential benefits of advances in technology such as mobile apps to help people with diabetes and improve the efficiency of care. While there might not be any benefit to the participant at an individual level but this research might improve care for type 2 diabetes patients in the long-term. For participants allocated to the new model of care, there might be a greater improvement in blood glucose management as compared to usual care. This is as a result of being more focused on managing your diabetes through easy visualisation of your blood glucose data and text reminders. Also, this new model might be more convenient for patients with savings of time as compared to usual care – through efficient communication with the diabetes nurse.

8 What are the possible disadvantages and risks in taking part?

Possible risks, side effects and discomforts include feeling uncomfortable working with the mobile application, and the extra time required for entering your insulin doses into the mobile application. Over the course of this short study, sending the glucose readings' and insulin doses' data to the study database will use a small amount of internet data, less than 100MB per month. For some people this could mean a cost increase. This would depend on your mobile phone plan and your access to WiFi for internet usage rather than mobile phone network. If you are concerned that this data usage may increase your mobile phone costs, a member of the research team can help you to set a feature on your smartphone settings which limits the internet data usage conducted on the phone network. This would help avoid going over the usage set by a mobile phone plan.

There can be unforeseen technical issues, which will be addressed to by the technical team at CSIRO as soon as possible. Please contact Dr Anish Menon on 07 31768187 for technical-related issues.

9 What do I do if I wish to withdraw from the research?

If you wish to withdraw from this study, please advise the study team. You will be asked to complete and sign a "Withdrawal of Consent' form which is included with this form.

10 What happens when the study ends?

When this study finishes, you will continue to receive your routine service from the clinic as other non-participants. For participants using the new model of care, following the end of the study there will be limited access to the mobile app. You will be able to visualise your prior recorded blood glucose data but will not be able to communicate via the app; email your report and will not receive text messages. The research team in conjunction with the clinical staff will analyse the data and future roll-outs of this system will depend on the results of the study.

Part II – How is the study being conducted?

11 What will happen to information about me?

Stringent processes will be used to ensure that the data and identity of people participating in the study are confidential. Information collected for this study will be stored on secure servers in CSIRO. In addition to your routine health care providers, two people from the CSIRO technical team who administer the system will have access to the stored data. Reports on the study's results will be published, but individual participants will not be identifiable in these reports.
Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law.

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

12 Who is organising and funding the research?

This study is being conducted by team of researchers' from Queensland Health, CSIRO's Australian e-Health Research Centre, and The University of Queensland. The funding for this study has been provided by Queensland Health. You will not benefit financially from your involvement in this study project.

No investigator or member of research staff will receive a personal financial benefit from your involvement in this study.

13 Who has reviewed the study?

All research in Australia involving humans is reviewed by an independent group of people, called a Human Research Ethics Committee (HREC). This study has been reviewed and given approval by Metro South HREC.

14 Further information and who to contact

If you require further information or if you have any problems concerning this project, you can contact the principal researcher, Dr Anish Menon. The researcher responsible for this project and the telephone number is:
Dr Anish Menon 07 3176 8187

If you would like to talk to someone not directly involved with the study for any further information regarding your rights as a study participant or should you wish to make a complaint to people independent of the study team, you may contact the Human Research Ethics Committee (HREC) Coordinator, Metro South HREC, on (07) 3443 8049, email EthicsResearch.PAH@health.qld.gov.au.

This study adheres to the Guidelines of the ethical review process of The University of Queensland. If you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Officer on (07) 3365 3924.

PARTICIPANT CONSENT FORM

Title	**Mobile-based Disease Management System for insulin dose adjustment in type 2 diabetes for specialist outreach and diabetes telehealth service (REMODEL-IDA)**
Project Sponsor	**Queensland Health**
Principal Investigator	**Dr Anish Menon**
Location	**Princess Alexandra Hospital**
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1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I have been informed about the possible risks of taking part in this study.

4. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

5. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future health care.

Name of Participant	Signature of Participant	Date
Name of Member of Study Team	Signature of Member of Study Team	Date

Note: to be signed by the member of the study team who consented the participant to the study

WITHDRAWAL OF PARTICIPATION

Title	**Mobile-based Disease Management System for insulin dose adjustment in type 2 diabetes for specialist outreach and diabetes telehealth service (REMODEL-IDA)**
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I hereby wish to WITHDRAW my intent to participate further in the above research project and understand that such withdrawal will not jeopardise my future health care.

- Participant's Name (printed)

Signature _____

Date _____

In the event the participant decided to withdraw verbally, please give a description of the circumstances. Coordinating Investigator to provide further information here:

Coordinating Investigator to sign the withdrawal of consent form on behalf of a participant if verbal withdrawal has been given:

- Participant's Name (printed)

Signature _____

Date _____