### INFORMATION SHEET FOR PARTICIPATION IN RESEARCH

**Project Title: Impact of Self-care Education through Mobile Phone Application Intervention on Diabetes Patients: a Randomized Controlled Trial**

You are invited to take part in the above named research. The study aims to determine if the health outcomes and self-care activities of diabetes patients will improve when they receive health education support through text messages on mobile phone application. The knowledge from this study will be of great value in deciding best ways to promote diabetes self-care education.

The study is being conducted by Mary Adu (PhD Candidate) and it will contribute to a degree in Doctor of Philosophy (Health) at James Cook University.

Involvement in this study

Your participation in this research is voluntary, while we would be pleased to have you participate, we respect your right to decline. Your decision whether or not to participate will not affect your present and future relationship with the Townsville Teaching Hospital or the Community Health Services, Kirwan. You can stop taking part in the study at any time without explanation or prejudice. You may also request that the information you have supplied be removed.

What procedures are involved?

If you agree to be involved in the study, the key procedures involved in the research project are:

Survey questionnaire (recruitment and 12 months) and Randomization

At recruitment, the principal investigator will provide you with a questionnaire that will be used to explore the following about you: personal and demographic information, knowledge of diabetes management, medication taking habits, family and medical history of diabetes. It will also ask about how you perceive your wellness and the ability to self-manage diabetes. At the end of the study which is 12 months, questionnaire will again be provided to you to ask about knowledge of diabetes management, medication taking habits, perception on wellness and ability to manage diabetes. The questionnaire will take about 15 – 20 minutes of your time.

A computer randomization tool will be used to allocate you into one of the two groups.

*Group 1 participants*

 If you are allocated to Group 1, you will continue to receive usual diabetes clinical care only. You will be required to visits the clinic at 4, 8 and 12 months of the study. These visits are part of the regular check up with your doctor.

*Group 2 participants*

If you are allocated to Group 2, in addition to usual diabetes clinical care and visits to the clinic at 4, 8 and 12 months of the study, you will be required to download a mobile diabetes application (app) onto your smart mobile phone and through this device, you will receive health messages once a week on how you can improve diabetes management. The mobile diabetes application will be provided at no cost to you.

*Recording of Parameters:* The application has an added feature where you can input measurements and activities you took at home in regards to your blood glucose, physical activities and diet. Anytime you input these records, it will provide you a personalised educational feedback on how to improve or maintain your diabetes management. To assess how best this application work for you, we suggest you input those measurements at least twice a week; once on a weekend and once during the week days. These measurements inputted into the app will be sent to the principal investigator through a secured web interface and stored onto a pass-word protected computer system in an aggregated de-identified format and will not be linked with your phone number or your name.

What happens to the application after the study: After the study, you will still have access to the application. However, this will be limited to basic functions. If you wish to retain access to the full range of functions (such as technological upgrade and customised automated messaging systems), you will need to subscribe at a reduced rate for these services.

Collection of medical information

At the end of the study, the research team will collect information about your health from your health records at the hospital where you attend your diabetes clinic for all participants both in Group 1 and 2. Data collected will be records of your Fasting Blood Glucose, HbA1c, lipids, blood pressure, weight, height, waist circumference, Urine Creatinine and albumin ratio, prescribed medications, emergency hospital visits and other vital information related to diabetes management for the time you were in the study. These records are usual part of your routine care, so you will not be required to provide them separately for this study.

What are the potential risk?

There are no risk anticipated with participation in this study. You will still continue with your usual care irrespective of the study group you are allocated to. The data collected from the mobile phone from group 2 participants will not identify you, your phone number and your name will not be recorded. All data will be electronically and securely stored for at least 15 years as required by the Australian Code for the responsible conduct of research.

What about privacy and confidentiality?

Your responses and information collected from your medical record will be given a unique code and you will not be personally identified. The data from the study will be used in research publications and reports. Your names and other identifying details will not be included in any way in these published data.

Recruitment

If you are interested to participate in the study, kindly inquire about the principal investigator who will be present in the waiting room at your next clinic visit.

Who Should I contact if I have any questions or want to participate in the study?

If you want to participate or have any question about the study, please contact Mary Adu and /or Dr Bunmi Malau-Aduli, whose contact details are provided below:

Principal Investigator: Primary Supervisor:

Name: Mary Adu Name: Dr Bunmi Malau-Aduli

College: Medicine and Dentistry College: Medicine and Dentistry,

James Cook University James Cook University,

Tel: +61 469738375 Tel: +61 747814418

Email: mary.adu@my.jcu.edu.au Email: bunmi.malauaduli@jcu.edu.au

*If you have any concerns regarding the ethical conduct of the study, please contact:*

*Human Research Ethics Committee chairperson*

*Phone: 4433 1440*

*Tvs-Ethics-Commitee@health.qld.gov.au*

*Or*

*Human Ethics, Research office*

*James Cook University, Townsville, Qld 4811*

*Phone: (07) 4781 5011 (**ethics@jcu.edu.au**)*

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| **INFORMED CONSENT FORM**

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| **Principal Investigator: Mary Adu** |
| **Project Title: Impact of Mobile Phone Diabetes Application Intervention on Diabetes Patients: a Randomized Controlled Trial.** |
| **College: Medicine and Dentistry, James Cook University** |

I understand that the aim of this research study is to examine the impact of using mobile phone diabetes application to promote self-management amongst diabetes patients. I consent to participate in this study, the details have been explained to me, and I have been provided with a written information sheet to keep.I understand that my participation will involve the following procedures:* Completion of questionnaires at recruitment and 12 months of the study. The questionnaire will seek information about myself, knowledge of diabetes, medication taking habits, family and medical history of diabetes. It will also inquire about my perception of self-care for diabetes and wellness.
* I will be asked to use a mobile phone diabetes application for 12 months (if applicable).
* I understand that as part of my routine care, I will attend clinics at 4, 8 and 12 months of the study
* I will be followed up on my diabetes self-care for the duration of 12 months
* I understand that there will be a retrospective check of my clinical data only for the duration for which I am in the study.
* I agree that the researcher may use the results as described in the information sheet.

I acknowledge that: * Taking part in this study is voluntary
* Any risk or benefit of participating in this study have been explained to my satisfaction
* That any information I give will be kept confidential and that no names will be used to identify me with this study without my approval.

I consent to be part of this study |
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| **Printed Name:**  |
| **Date of Birth:**  |
| **Mobile Phone no: Best time to contact:**  |
| **Email:**  |
| **Signature**: Date: |

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|  **Declaration by study researcher**I have given a verbal explanation of the research project, its procedures and risks and believe that the participant has understood that explanation.

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| Name of study researcher\*:……………………………………………………………………….Signature: …………………………………………. Date: …………………………… |

\*A member of the research team must provide explanation of, and information concerning the research project. Participants Identification Code: \_\_ \_\_ \_\_ (office use only) |
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