# INFORMED CONSENT FORM

## 1. Study Information

### Protocol Title:

Integrated Tele-monitoring and Personalised Diabetes Management (IT-PDM) through blue-toothed glucometers in Insulin-Treated Patients: A Randomised Controlled Trial

### Principal Investigator & Contact Details:

Ms Lian Xia
11 Jln Tan Tock Seng, Singapore 308433
Phone Number: 63571000

### Study Sponsor:

Ng Teng Fong Health Innovation Programme

## 2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you are a patient with diabetes on insulin treatment, which is being newly started, or require significant dose adjustment during your current inpatient stay or outpatient visit.

This study is carried out to evaluate the efficiency of the use of a free mobile app for transfer of self-monitoring of blood glucose (SMBG) results to the healthcare team.

This study will recruit 120 subjects from Tan Tock Seng Hospital over a period of 22 to 28 weeks. About 120 subjects will be involved in this study.

## 3. What procedures will be followed in this study

If you take part in this study, you will be randomised to be in the intervention group (using mobile phone app) or the control group (using manual logbook). Randomisation means assigning you to one of two groups by chance, like tossing a coin or rolling dice.

If you belong to the intervention group, you will be required to download the mobile phone app is called “MySugr”. It is an open-source app that is free for download and is not specific for this study. This app allows glucose readings taken from a compatible, blue-toothed enabled glucometer to be sent directly onto the app. You can also use the app as a diary to indicate certain events or activities relating to diabetes management. Our study member will assist in helping set up the app and teaching you the use of the app. You will also be required to transfer your glucose readings every two weeks to a dedicated email that will be accessed only by members of the research team.

If you take part in this study, the standard care provided will be (1) follow the recommended frequency in SMBG monitoring, (2) charting your SMBG readings and other DM related information, (3) accept telehealth consultation in the first 6 weeks, and your usual clinic

consultations with usual blood test in the next 7-12 weeks and 22 -28 weeks.

If you take part in this study, the research components will be (1) use of mobile app, (2) answering questionnaires relating to quality of life and distress from diabetes.

Your participation in the study will last 22 to 28weeks. You will be expected to do close SMBG monitoring for about 6 weeks and be followed up for 22 to 28 weeks. You will need to visit the doctor's office two times in the course of the study.

If you agree to take part in this study, the following will happen to you:

| **Time/ Visit** | **Standard Assessments** | **Research** |
|---|---|---|
| **Week 0**<br>(Before discharge) | -Body weight | -Complete research questionnaires |
| **Week 0 to week 6**<br>(After discharge) | Report SMBG records to healthcare team every 2 weeks via phone call | Transfer SMBG records to healthcare team<br>every 2 weeks via dedicated email |
| **Week 7 to week 12** | Routine clinic visit and HbA1c will be taken for routine clinical tests | |
| **Week 22 to week 28** | Routine clinic visit and HbA1c, Lipid panel will be taken for routine clinical tests<br>-Body weight | -Complete research questionnaires |

In total, approximately 11ml of blood will be collected for clinical tests, HbA1c and cholesterol levels (lipid panel) requested by your diabetes doctor as part of your routine follow-up. When your participation in the study ends, you will still have access to the glucometer provided to you at the beginning of the study. You can still use the free mobile app for your own use. If you still prefer to send you SMBG reports to your healthcare team, you will need to make special additional arrangements with your healthcare team.

Any individually-identifiable data obtained during the course of this study will be stored and analysed for the purposes of this study and will not be used for future biomedical research, or shared with other institutions/ companies.

"Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. There will not be any incidental findings arising in this research.

## 4. Your Responsibilities in This Study

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to visit the hospital 2 times and undergo all the procedures that are outlined above.

## 5. What Is Not Standard Care or is Experimental in This Study

The study is being conducted because the use of handphone technology to monitor diabetes and to assist in diabetes management is not yet proven to be a standard treatment in subjects with diabetes on insulin treatment. We hope that your participation will help us to determine whether the use of technology in the form of mobile app is equal or superior to existing treatment using manual logbook.

Questionnaires completion will be part of research.

Use of randomization (study intervention by chance) are only done for research studies.

## 6. Possible Risks and Side Effects

As you are on insulin therapy, you may experience hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) symptoms. The diabetes nurse will educate you on necessary self-management at the beginning of the study. The nurse will contact you at scheduled tele-health consultations and will not be available for emergency situations.

There may be technical error, where your SMBG readings are not transferred to the mobile phone app (for participants in intervention group). In these situations, you should contact the diabetes nurse within the next 1-2 working days to troubleshoot.

If you are in the intervention group and randomized to the group using the free, commercially available mobile phone app, you will have to agree to the terms and conditions of the designers of the mobile phone app.

If you experience any new symptoms, you should contact your doctor or the Principal Investigator as soon as possible.

As you will be setting up an account to use the mobile App, you will have to agree to the terms and conditions set out by the mobile App company. There is a risk of privacy breach since your information will be stored by the mobile App on an external server.

However, there will be no sharing of information between the mobile App company and the hospital.

## 7. Possible Benefits from Participating in the Study

If you participate in this trial you may reasonably expect to benefit from the trial in the following way: 1) Closer monitoring and analysis of SMBG by diabetes nurse, 2) Closer titration of insulin therapy to achieve target.

## 8. Important Information for Women Subjects

There is no effect on pregnancy or risks specific to women subjects.

## 9. Alternatives to Participation

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be follow-up with the outpatient clinic. The outpatient appointment will be as per standard care.

## 10. Costs & Payments if Participating in the Study

If you take part in this study, the following will be given at no charge to you:

1. Glucometer x 1 unit
2. Test strips
3. Lancet

You will be reimbursed for your time, inconvenience and transportation costs as follows:

- You will be reimbursed $20 in vouchers at each clinic visit.
- These costs will be borne by Ng Teng Fong Health Innovation Programme.

If you take part in this study, you will have to pay for the following:

- Doctor's consultation as planned
- Routine blood tests as part of the study, or as requested by doctor in charge

We do not anticipate that you will incur any additional expenses as a result of your participation in this research. If there are any extra clinic visits or tests not relating to the research required, these costs will be borne by you.

**11. Voluntary Participation**

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, you will not be required to return all the DM consumables (Glucometer 1x, test strips, Lancet).

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the Principal Investigator or his/her representative.

**12. Compensation for Injury**

If you follow the directions of the doctors in charge of this study and you are physically injured due to the procedure given under the plan for this study, Tan Tock Seng Hospital will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by the Tan Tock Seng Hospital.

Tan Tock Seng Hospital without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove Tan Tock Seng Hospital is at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

**13. Confidentiality of Study and Medical Records**

Your participation in this study will involve the collection of “Personal Data”. “Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Information and “Personal Data” collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

To protect your confidentiality, only a unique code number will be used to identify data that we collect from you.

However, the Sponsoring company (Ng Teng Fong Health Innovation Programme), Regulatory Agencies and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorising (i) the collection, access to, use and storage of your “Personal Data”, and (ii) the disclosure to authorised service providers and relevant third parties.

Data collected and entered into the Case Report Forms are the property of Tan Tock Seng Hospital. In the event of any publication regarding this study, your identity will remain confidential.

Research arising in the future, based on your “Personal Data”, will be subject to review by the relevant institutional review board.

By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at https://www.ttsh.com.sg/Patients-and-Visitors/Your-Hospital-Stay/Pages/Patients-Rights.aspx .

**14. Who To Contact if You Have Questions**

If you have questions about this research study, you may contact the Principal Investigator, Ms Lian Xia, Phone number 63571000.

In case of any injuries during the course of this study, you may contact the Principal Investigator, Ms Lian Xia, Phone number 63571000.

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

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I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction.

By participating in this research study, I confirm that I have read, understood and consent to the TTSH Personal Data Protection Notification.

| _____ | _____ | _____ |
|---|---|---|
| Name of Participant | Signature of Participant | Date |

**Witness Statement**
I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant signing this informed consent form has the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

| _____ | _____ | _____ |
|---|---|---|
| Name of Witness | Signature | Date |

1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.
2. However, if the participant is unable to read, and/ or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the study team.

**Investigator Statement**
I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the study.

| _____ | _____ | _____ |
|---|---|---|
| Name of Investigator / Person administering consent | Signature | Date |