SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study. Your participation in this study is entirely voluntary. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document.

STUDY INFORMATION

Protocol Title:
Integrated **C**ontinuous glucose monitoring glycemic c**HA**racterization during **P**regnancy in comparison with OGTT (I-CHAP)

This research study is recruiting at the following SingHealth institution(s). Please note that the word "SingHealth" refers to the institution where you are recruited into the study.

KK Women's and Children's Hospital
Principal Investigator:
Dr Quah Phaik Ling
Senior Research Fellow
Department of Obstetrics & Gynaecology
Tel: 97732543
Institution Mainline: +65 6394 1099

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to contribute new knowledge by examining the use of electronic devices that you can wear on your body. More specifically, we want to know if sensors you wear on your body that can track your sugar level throughout the day called the continuous glucose monitor (CGM)can improve patient care and be a potential replacement to the routine oral glucose tolerance test (OGTT). All pregnant women undergo the OGTT for the diagnosis of diabetes during pregnancy that we term gestational diabetes mellitus (GDM). Before you take part in this research study, the study must be explained to you, and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

You were selected as a possible participant in this study because you are pregnant and attending KK Women's and Children's Hospital for antenatal consultation. You have to be pregnant and have not undergone your OGTT.

The study's main aim is to establish much needed preliminary evidence in our Asian population to show the capabilities of CGM use and its wealth of data for GDM diagnosis.

This study targets to recruit 80 participants from KK Women's and Children's Hospital.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to take part in this study, a consent form will be signed. You will also receive education from the study team on how to apply the Dexcom continuous glucose monitoring (CGM) device on your own 3 days before your scheduled OGTT. At the end of the 10-day wear, peel off the sensor like a plaster and dispose normally. You will also be given a glucose data receiver which you must carry with you for the 10-day duration of your CGM wear.

Figure 1 shows you how the CGM device looks like, and Figure 2 shows you how it will be worn on the back of your upper arm.

The application of this sensor is painless and will only take a few seconds.

At your next routine antenatal clinic visit, you must return the glucose data receiver to the study team before the study team can provide you a copy of your glucose data for your reference.

Data obtained during this study will be stored and used only for the purposes of this study.

These data will not be used for future research.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- Put on the continuous glucose monitoring (CGM) 3 days before your OGTT
- Remove the sensor only after your 10-day wear
- Return the glucose data receiver to the research team at your next antenatal clinic visit
- Complete the questionnaires provided at your next antenatal clinic visit which will take approximately 10 minutes

The study involves the following:

Study device:
Application of Dexcom CGM sensors

The study team will educate you on how and when to apply the G6 Dexcom CGM sensor on either your right or left arm once the consent form has been signed, and once you have been recruited as a participant of the study. You will be advised on when to apply the CGM sensors, and to complete a 10-day wear-time.

There are no safety risks since the sensor's battery is waterproof. You are free to take a shower or swim with it anytime. Such device has been approved by Singapore Health Science Authority (HSA).

Glucose data

The study team members will be downloading your glucose data to the Dexcom CLARITY online website and your data will be stored temporarily in a secure Cloud. Your patient information will be de-identified and only your Subject ID will be used to tag your glucose data. Only the study team will have access to this data and the data will be deleted when your account is no longer active.

Baseline demographic information

We will be collecting some baseline demographic information from you, but no personal identifiers.

Questionnaires

At your next routine antenatal clinic visit, you will be asked to self-report your OGTT date, timing of the first blood draw, GDM diagnosis and treatment received. You will also be given a feedback survey questionnaire to fill in.

Maternal obstetrics and neonatal outcomes

Your maternal obstetrics outcomes and neonatal birth outcomes will be retrieved from the hospital medical notes.

Figure 1: The Dexcom G6 continuous glucose monitoring (CGM) sensor. The Dexcom G6 measures 70mm X 40mm X 10mm, and weighs 11.9 grams.

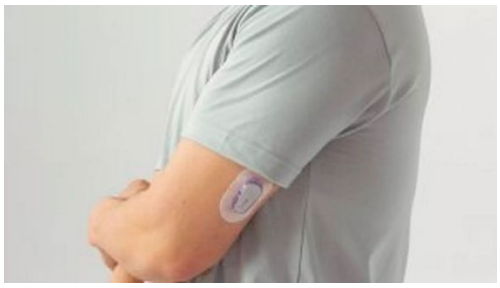

Figure 2: The Dexcom G6 sensor placement on the upper arm

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

The glucose monitoring sensor is not part of routine assessment and is not meant for diagnostic or screening purposes. We hope that your participation will help us to determine whether the sensor is well tolerable and acceptable in pregnant women.

In this study, the introduction of the use of the Dexcom G6 CGM is being performed for the purposes of the research and are not part of your routine care.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

There will be minimal risks because the continuous glucose monitoring system has been tested to be minimally invasive and has low irritability to pregnant subjects. There will not be any possible risks on the sensor's battery and it is water proof. The participants wearing this device is free to take a shower or swim with it anytime. However, local bruises and skin rashes might be possible even though low in likelihood, and it is not widely reported in previous studies.

Questionnaires/ surveys/ interviews:
Some of the questions might make you feel uncomfortable or upset. You may refuse to answer any of the questions and/or take a break at any time during the study.

POTENTIAL BENEFITS

If you participate in this study you may reasonably expect to benefit from the study device as this project is the first to look at a possible ways to incorporate the use of the CGM technology into pregnant patient care for diagnosing GDM. You will also be receiving a copy of your glucose data from the 10-day wear.

ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution, the standard care involves your routine antenatal visits at KKH.

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

You will be reimbursed for your time, inconvenience and transportation costs as follows by the study team:

- If you complete the study and return the glucose receive to the study team, you will receive SGD50 for the first baseline visit and the second clinic visit.
- You will be receiving SGD100 in total for the completion of both visits

The Dexcom CGM sensors will be provided to you at no cost.

The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you.

INCIDENTAL FINDINGS

"Incidental findings" are findings that have potential health or reproductive importance to a participant like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may cause you to feel anxious and may affect your current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study),

It is possible that incidental findings may be detected or suspected in the course of conducting the study. As this is research and there is no intention to perform medical diagnosis, the medical significance of the incidental finding may not be clear. Hence, there is no notification for incidental findings.
Please note that the readings from the CGM devices may differ from that of the OGTT. This is because the CGM samples glucose from the interstitial fluid, and not the blood which might account for minor discrepancy in the values. However, we do expect the glucose readings from both the CGM and the OGTT to be very similar in terms of the trends.

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation in the study at any time, without your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, all study procedures will be discontinued. However, the data that have been collected until the time of your withdrawal will be kept and analyzed. The reason is to enable a complete and comprehensive evaluation of the study.

The Principal Investigator of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- You are strongly against wearing the glucose monitoring sensor due to severe skin irritation or mentally stress.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the medical device given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

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. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential and stored in Singapore. Your study records and medical records (if applicable), to the extent required by the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access. In the event of any publication regarding this study, your identity will remain confidential.

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records (if applicable) and study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by SingHealth, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will SingHealth and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.

All data collected in this study are the property of SingHealth and will be used for the purpose of this research study only.
By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 8126 3660 during office hours (8:30 am to 5:30pm).

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact your study doctor, the Principal Investigator listed under STUDY INFORMATION section, at the beginning of this document.

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM FOR RESEARCH STUDY

Protocol Title:
Integrated **C**ontinuous glucose monitoring glycemic c**HA**racterization during **P**regnancy in comparison with OGTT (I-CHAP)

Declaration by Research Participant

(i) I agree to participate in the research study as described and, on the terms, set out in the Participant Information Sheet. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

(ii) I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

(v) I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

(vi) By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for _____ (Name of Participant) to participate in the research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

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

Witnessed by: _____ _____

Name of witness Date of signing

_____

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

Name of Investigator/ Person obtaining consent	Signature	Date