Scimita Operations PTY LTD
ACN: 614 606 852
PO Box 164 | Arncliffe NSW 2205 | Australia

Participant Information Sheet and Consent Form

Date:15 July 2020

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Participant Information Sheet and Consent Form

Title	Non-invasive monitoring to translate the biometric data of participants with diabetes into blood glucose levels
Principal Investigator	Dr Thomas Telfer
Coordinating Investigator	Dr Farid Sanai
Co-investigators	Dr Benjamin Kwan, Dr Shane Cox, David Wang, Dr Mobin Nomvar, Lachlan Boyle, Arshman Sahid
Sponsor	Scimita Operations Unit 31/2 Bishop Street, St Peters NSW 2044

1 INTRODUCTION

You are invited to participate in this clinical study because you have responded to our online advertisement and have satisfied our inclusion and exclusion criteria. You have indicated that you are a person living with type 2 diabetes and are interested in assisting us with the development of a new, non-invasive technology for blood glucose monitoring which will have the potential to eliminate the need for painful finger pricking or expensive continuous blood glucose monitor use.

This study will involve collection of a selection of biometric data over a two-week period. You will be asked to wear a non-invasive custom-built device that will collect continuous biometric data which will include bioimpedance (a measure of how resistive and capacitive your skin is), near-infrared spectroscopy (a measure of how well your skin absorbs light of specific types), vital signs (pulse rate and skin temperature), and galvanic skin response (a measure of sweat gland activation). You will also be asked to use this device together with two existing commercially available blood glucose meters throughout the duration of the study (an Abbott FreeStyle Libre and an Accu-Chek® Mobile). If you are currently using a device other than the two mentioned, you will be required to continue using those as a part of your ongoing regular care. We will be using the data collected from the non-invasive custom-built device and the existing blood glucose meters to develop a computer model that will enable us to predict your blood glucose level over time. Once

this computer model has been developed, we will be able to predict your blood glucose level using only the data from the non-invasive custom-built device.

PLEASE NOTE: at no point within the study, should you deviate from any management plan (including the use of blood glucose monitoring), provided to you by your regular doctor, under your regular care. This is an observational study only.

There may be some words or phrases in this document that you are not familiar with. Please do not hesitate to ask any of the Investigators any questions, for any information to be explained differently, or for additional information about anything you are curious about. Anything that you may not understand will be addressed until you are satisfied.

Please read this document carefully. This document contains all the details you might like to know about, such as the purpose of study, risks, benefits, data acquisition, and data storage involved in this study. Knowing this information will help you decide if you wish to be involved in our research. It also includes a Consent Form that contains information regarding your roles and responsibilities as a study participant.

Participation in this clinical study is entirely voluntary. If you don't wish to take part, you are under no obligations to do so. Before deciding if you wish to take part, you might want to talk about it with a relative or a friend. If you do decide to take part in the study, you will be asked to sign the Consent Form as a record of informed consent.

By signing the Consent Form, you are telling us that you:

- Understand what you have read and have sought further clarification about anything you did not understand
- Consent to take part in this study
- Consent to participating in the procedures for data collection, as detailed
- Consent to use of your personal and health information, as detailed

You will be given a copy of this Participant Information Sheet and the completed Consent Form to keep for your own reference.

2 WHAT IS THE STUDY ABOUT?

Diabetes is a chronic health condition that occurs when the pancreas does not make sufficient insulin (type 1) or when the body cannot effectively use the insulin already produced (type 2). Both

types of diabetes can lead to high blood glucose levels. Chronically high blood glucose levels can cause serious complications such as retinopathy, neuropathy, and cardiovascular disease. According to the International Diabetes Federation, in 2019, 463 million people worldwide and 1.3 million people in Australia were affected by diabetes.

Monitoring blood glucose levels is crucial to diabetes management. There are currently two main methods for individuals living with diabetes to monitor their own blood glucose levels:

- Invasive self-managed blood glucose meters (such as the Accu-Chek Mobile). These are the most accurate devices. A typical individual with diabetes is asked to prick their finger at least 5 times a day, however, which means this invasive method can become increasingly uncomfortable over time with the added risk of infection or injury, contributing to common non-compliance.
- Semi-continuous or continuous blood glucose monitoring systems (such as the FreeStyle Libre). These reduce the abovementioned complications but are expensive, consumable products that are still invasive and can cause discomfort. They have low market penetration for these reasons.

There is a strong push from clinicians and individuals living with diabetes for an affordable, non-invasive, continuous blood glucose monitor that can overcome all the identified issues with existing devices. Development of such a device is seen as the next major step in diabetes management. The first truly non-invasive continuous blood glucose monitor is currently in development. The purpose of this study is to collect biometric data from a group of participants who are living with type 2 diabetes. This biometric data will be used to develop and refine our computer model that can be used to calculate blood glucose levels from data collected from a non-invasive wearable device that has been custom built for data collection. It is important that our volunteers are people living with type 2 diabetes so that data can be generated across a range of blood glucose levels to ensure this computer model is robust.

3 WHAT DOES PARTICIPATION IN THE STUDY INVOLVE?

You have so far expressed your interest by taking part in our online survey. From this we have determined that you are able to take part in this study, having met our eligibility criteria and you have received this Participation Information Sheet because you have passed through our screening process and are eligible to be enrolled in the study.

You have been invited to the Sponsor site for enrolment, during which you have been provided with this Participant Information Sheet and will provide informed consent. You will next be asked to

complete a second online survey which will ask you questions about your time availability, typical day-to-day activities (e.g. when you eat meals, what your typical work activities and commitments are, what your typical exercise habits are, and what you typically do in your leisure time), and your current practices for monitoring your blood glucose level. Please note that both surveys are conducted through a link provided which is connected to Sponsor's website (platform used for the surveys). Information generated during the initial screening survey and the secondary online survey will be immediately transmitted and stored on a secure cloud server. No additional copies of this information will exist

If you have not recently had a blood test to check your haemoglobin A1c level, we will provide you with a pathology request form for a blood test. We will have already paid the cost of this blood test. Your haemoglobin A1c level provides information on your average blood glucose level over the past 3 months. We will also measure you for size such that we can manufacture your personal non-invasive, custom-built device. It is anticipated that it will take about 4-5 days from enrolment until the time a fitted device can be prepared and fitted for you.

Pending your consent and your haemoglobin A1c level results, you will be enrolled into the study. Once you are enrolled in this study it is important that you attend all visits on the scheduled dates. The study Investigators will schedule these dates to fit in with your schedule once you are enrolled in the study and will remind you of upcoming appointments.

Once you are successfully enrolled in the study, you will be asked to attend the Sponsor site for the following visits:

- **Visit 1 (study day 1): Training and Education.** You will be provided with all the devices and software you will use during the study and you will be trained in the study processes.
- **Visit 2 (study day 8): Monitoring at the Sponsor Site.** You will attend the Sponsor site during which time you will collect data as normal but in our controlled environment.
- **Visit 3 (study day 15): Monitoring at the Sponsor Site.** You will again attend the Sponsor site during which time you will collect data as normal but in our controlled environment. This will mark the end of the study and you will return your personal non-invasive, custom-built device.

Each visit will last approximately 4 hours and you will be compensated for your time. The study will last a total of 15 days. As much as possible, we will schedule the timing of your visits at your best convenience. We will provide you with details of the relevant technical Investigator and information on how to contact them in case of any technical issues. Detailed descriptions of each visit, as well as information on what will happens between visits is summarized in the figure below.

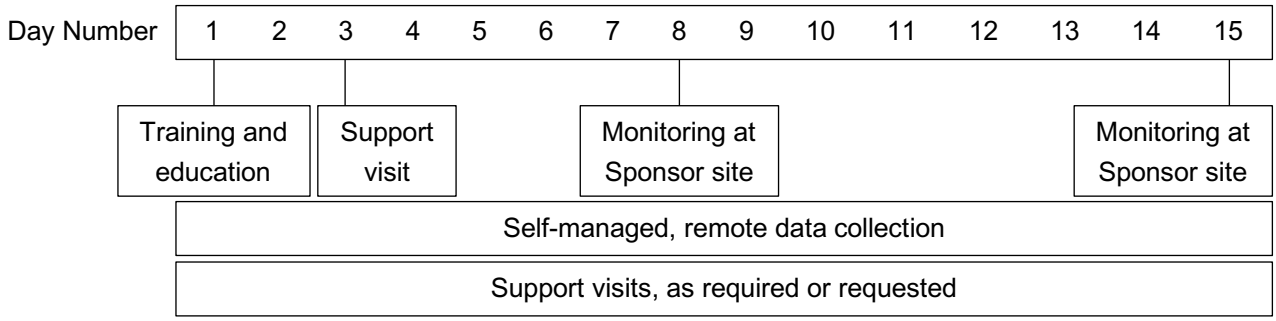

Figure 1: Diagram showing the key milestones over the 15-day study duration.

Visit 1: Training and Education (study day 1)

During this visit, you will receive your personal non-invasive, custom-built device (See Figure 2). You will be trained on how to use this device. We will also assist you with the installation of a custom-developed app onto your phone (if you own an iOS device) or alternatively, we will provide you with an internet-enabled mobile phone with the app pre-installed. We will assist you with installation of a FreeStyle Libre blood glucose meter and provide you with an Accu-Chek Mobile blood glucose meter. We will explain when and how each of these devices need to be used and will collect a small amount of data with your assistance to confirm that everything is working correctly.

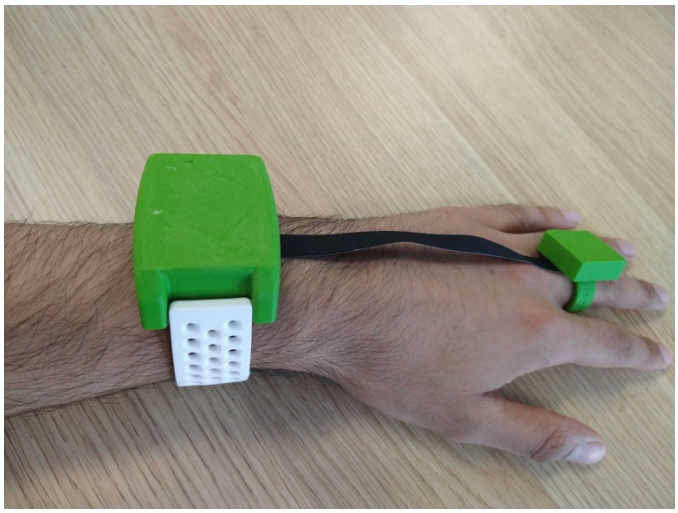

Figure 2: A sample of the prototype device you will be wearing on your non-dominant hand. It includes a wearable watch that is connected to a ring via a detachable cable.

Remote: Self-Managed, Remote Data Collection (study day 1 – 15)

You will be asked to carry out your regular day-to-day activities over the remainder of the study. During this time, you will need to be wearing your personal non-invasive, custom-built device at all

times (except when washing or showering), to allow us to collect real-time biometric data that is uploaded directly into our secure cloud storage. You will be asked to take your own blood glucose level measurements at defined intervals each day using both the FreeStyle Libre and Accu-Chek Mobile. These intervals are, immediately before every meal, 2 hours after every meal, and before going to bed. Additional blood glucose measurements taken before and after exercise or if you are feeling unwell will also be requested. The app will also prompt you to take your measurements. You will also be asked to keep a log of activities such as eating and exercise in the app.

Remote: Support Consultation (study day 3)

For day 3 of the study, we will schedule a support consultation with you to ensure everything is working correctly and provide you an opportunity to ask any questions. This will be conducted remotely via the use of video conferencing or if not possible, teleconferencing. If there are any issues, the Investigators will work to best resolve any issues you have.

Visit 2: Monitoring at the Sponsor Site (study day 8)

On day 8 of the study, you will attend the Sponsor site where you will have the opportunity to raise any questions you have about the device, provide feedback, and diagnose any issues. During this visit we will also collect some data under a controlled environment for 4 hours. You will be compensated for you time. You will be asked to take blood glucose measurements up to every 20 minutes during this 4-hour period. Refreshments will be provided for the duration of your attendance.

Visit 3: Monitoring at the Sponsor Site (study day 15)

On day 15 of the study, you will again attend the Sponsor site for a final visit. You will have another opportunity to provide the Investigators with feedback. We will collect some more data under a controlled environment for 4 hours. You will be asked to take blood glucose measurements up to every 20 minutes during this 4-hour period. Refreshments will be provided for the duration of your attendance. Following this, the study will conclude and you will return your personal non-invasive, custom-built device. You will receive your reimbursement at this time.

Please note, you are required to continue using of your own routine CGM or any other monitoring devices throughout the study as per your normal routine. These may happen to be similar to one or both of the devices used for the study (i.e. Accu-Chek and Freestyle Libre).

Please note the following:

- The device is for your personal use only and should not under any circumstances be shared with anyone else.
- Please do not attempt to open the device or any of its components, as this may lead to damage and will affect the ability of the device to generate meaningful data.
- If the device is damaged as a result of an accident or if you notice any damage, please do not hesitate to contact the coordinating investigator on 1800 866 255, and we will organise a replacement for you as soon as possible, so that you can continue on with the study.

4 DO I HAVE TO TAKE PART IN THIS RESEARCH PROJECT?

Participation in this study is entirely voluntary. You have no obligation to take part. You are free to withdraw at any time without having to provide a reason. Please note the if you do withdraw from the study, any data that has been collected up until that time will be retained.

Whatever your decision, please be assured that it will not affect your routine treatment, your relationship your healthcare professionals, or your relationship with Diabetes Australia

5 WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You will not directly benefit from taking part in this study but the information we collect may ultimately lead to the development of a blood glucose monitoring device that is non-invasive, continuous, pain-free, accurate, and affordable, with the potential to significantly improve the management of diabetes and improve quality of life for people living with diabetes.

We will retain your contact information and offer to provide you with informative updates about our product development as we proceed further through our development of the non-invasive continuous blood glucose monitor. We will reimburse you for your time and for your travel to the sponsor site.

6 WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?

This study is non-interventional and does not interfere with your diagnosis and treatment. As such, there are minimal risks involved. We have strict exclusion criteria to eliminate as many risks associated with participant factors as possible.

There are minor risks associated with the use of the existing blood glucose monitors (FreeStyle Libre or Accu-Chek Mobile). There is a possibility of mild discomfort and local irritation while using

the wearable device (similar discomfort to wearing a watch for a long time). The non-invasive device has been designed so as to minimise the risk of contact allergy but that it remains possible that there will be some local irritation. Participants should contact the study team urgently should there be any swelling of the skin in contact with the device.

The Freestyle Libre sensor applicator contains a small needle that is used as a guide and will be inserted under the skin to apply the sensor. Once the sensor is attached the needle is removed. There is a possibility of some pain and discomfort when using the applicator to apply the sensor due to the needle insertion and wearing of the device. You are required to wipe the area where the sensor is being applied, using alcohol wipes."

The use of Accu-Chek device requires you to prick your fingers with a lancet provided which could also cause minor pain and discomfort when taking blood glucose measurements using this device. You are required to wipe the area where the finger is to be pricked using alcohol wipes."

These devices will be used as per the manufacturer's instructions. We will provide you with instructions on how to safely use these devices during your first visit and you will be able to contact the investigators throughout the study if you have any concerns or queries

If you have not recently checked your haemoglobin A1c levels, you will be required to do a blood test at a pathology laboratory under the care of trained professionals. There may be some minimal routine risks associated with taking a blood test. These may include discomfort and bruising at the site where the needle goes in. These are usually minor and go away shortly after the tests are done.

We have strict procedures in place to ensure the security of your data. All data will be de-identified and all data will be encrypted. In the unlikely event that data security is compromised, there is minimal risk that it can be interpreted or traced back to individual participants. Furthermore, the iOS App used in this study, does not include location services and does not access functionalities to back up any data other than the ones generated from the device (which will be of no significance to anyone but the investigators). This data is only accessible by investigators, either through direct download or through encrypted cloud storage.

The non-invasive, custom-built device you will use in this study has been purpose built for this data collection study. This device is entirely non-invasive and serves the purpose of acquiring data only. It will not provide you with blood glucose information and thus cannot be used for a treatment decision. There are minimal risks associated with use of this device. Like other electrical devices on the market, the internal electronics are insulated and inaccessible to you. All material that is in

contact with your skin has been evaluated for safety. The device is compliant with relevant safety and operation standards. The device is battery powered and uses a battery suited to modern wearable devices. The non-invasive, system-built device should always be worn, as long as practical. This should not affect your daily routine.

There may be additional risks associated with this study that are not yet known or that are unforeseeable.

7 WILL I BE GIVEN THE RESULTS OF THE RESEARCH PROJECT?

You will not be provided with any blood glucose level information generated from the non-invasive, custom-built device. You will have access to the information generated by the existing blood glucose meters (FreeStyle Libre and AccuCheck Mobile) which may form part of your regular blood glucose monitoring routine. With your consent, we will retain your contact information and offer to provide you with informative updates about our product development as we proceed further through our development of the non-invasive continuous blood glucose monitor.

8 WHAT ARE THE COSTS INVOLVED?

This study is being conducted by Dr Thomas Telfer (Principal Investigator), Dr Farid Sanai (Coordinating Investigator), and the other Co-Investigators listed on this Participant Information Sheet. The study is funded by Scimita Operations. There are no financial benefits to you or the Investigators from your participation in this study. All procedures detailed in this Participant Information Sheet that are part of the study will be provided to you free of charge.

You will be reimbursed for expenses related to your participation in this study (e.g. parking or travel expenses). A tax invoice is required for reimbursement for these expenses. You will be compensated for your time with a $300 gift card for the full completion and participation in this study. This gift card will be provided once the study is complete.

9 WHO TO CONTACT IN CASE OF ADVERSE EVENTS?

If you have any medical problems which may be related to your involvement in this study (any adverse events or side-effects), you can contact the Investigators who will put you in immediate contact with the principal medical clinician for this study, Dr. Benjamin Kwan, who will assist you in arranging appropriate medical treatment. You should report any adverse events immediately to the

Investigators and you will be asked specifically about these during each support visit or visit to the Sponsor site. In case of emergency, please contact 000.

10 WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

Immediately after completing the initial online survey, you will be allocated a unique identification number. All data collected will be immediately de-identified such that it is tied only to your unique identification number and will be separated from your personal information (e.g. name and personal details) and only authorised personnel (Principal Investigator and the Coordinating Investigator), will have access to the password-protected databases containing your identifiable information. Your data will not be released for any use without your prior consent, unless required by law. Data will be stored under a study number, in a separate file so that on study completion, data cannot be identified during data analyses.

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

All collected data from devices used in the study will be encrypted to ensure security. All data will be transferred from the devices it is collected on to a paired mobile phone through a custom-built app. The mobile phone will periodically and regularly upload the data to a secure cloud server. Data may be stored locally in each device. These local stores will be backed up to the secure cloud store each time you attend the Sponsor site and all data will be removed from these devices at the conclusion of the study. No hard copies of any data generated throughout the study will be kept and there will be a restriction placed on producing hard copies. The secure cloud store may be backed up onto a locally stored hard drive periodically which will be kept in a locked, secure location at the Sponsor site.

11 WHAT HAPPENS IF THERE IS A NEW DEVELOPMENT MADE DURING THE STUDY?

You will be provided with information regarding any new developments made throughout the study. As a result, if there are any changes to the study or protocol, you will be kept informed and may be asked to give your informed consent again before proceeding with the study.

12 WHAT HAPPENS IF THE DEVICE GOES TO COMMERCIALISATION?

At any point after the completion of the trial, if a viable commercial product is developed, our research partner who we are developing the device with will claim ownership of the final product.

13 BANKING OF HEALTH INFORMATION

Banking is storing health information for future research studies. A bank is the place where the health information is stored.

The data collected from all the devices (the non-invasive, custom-built, FreeStyle Libre, and AccuCheck Mobile) will be transmitted to a paired mobile phone which stores the data locally. When the mobile phone is connected to the internet the stored data will be uploaded to a secure cloud store. All the data collected will be deidentified where each participants name will be replaced with their unique identification number. This data will not be shared with or given out to anyone. The records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available.

It is possible that this data would be useful in future research, audit and teaching projects, helping us to continually improve health outcomes and develop new treatment. Your data would be anonymised prior to being used for this work. If you do not wish your data to be used in any future research, after this study, it will not affect your participation in any way. There is a section on the consent form for you to sign that will allow us to use your data in this way.

We will not use your personal health information for a different research project without the permission of a Human Research Ethics Committee. Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the research project may be presented in public talks or written articles, but information will not be presented that identifies the participant.

Only the Investigators named in this Participant Information Sheet will have direct access to the data generated in this study. Authorization will be required to access this data. The Investigators and the Sponsor will permit study-related monitoring, audits, HREC review, and regulatory inspection where required by law which may include providing direct access to source data and documents.

The data will be stored for 15 years regardless of whether the project ceases or whether any Investigators cease employment at their current organisation. After 15 years the data will be

destroyed. Computer files will be permanently deleted from computers, hard-drives, and any other locations.

14 COMPENSATION FOR INJURIES OR COMPLICATIONS

If you suffer any injuries or complications as a result of this study, you should contact the Investigators as soon as possible, who will assist you in arranging appropriate medical treatment. 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.

If you are injured as a result of your participation in this investigation you may be entitled to compensation. Sponsors of clinical investigations in Australia have agreed that the guidelines developed by their industry body, Medical Technology Association of Australia (MTAA), will govern the way in which compensation claims from injured participants are managed by sponsors. However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines. These guidelines are available for your inspection on the MTAA website (www.mtaa.org.au) under Policy – Clinical Investigations. Alternatively, your study doctor can provide you with a hard-copy of the guidelines. It is the recommendation of the independent ethics committee responsible for the review of this investigation that you seek independent legal advice before taking any steps towards compensation for injury.

15 QUESTIONS

If you decide to take part in this study, please take as much time as you to need to ask us any questions. You are encouraged to discuss any questions you have with any of the Investigators, your family, or your friends. Do not sign the consent form unless you have had a chance to ask questions and have received an answer you are satisfied with.

16 WHAT HAPPENS IF THERE IS A FOLLOW UP STUDY?

If you agree to sign the consent form, you are only agreeing to participate in the study described in this Participant Information Sheet. After the completion of this study, we may re-contact you in the future to participate in subsequent follow up studies that may improve the function of the non-invasive, continuous blood glucose monitor that we are developing. You are under no obligation to participate in future studies. At the bottom of the Consent Form, we ask for your permission to be contacted in future. You may choose not to give us permission for this or to participate in future studies. This decision will not have an impact on your involvement in the study described in this Participant Information Sheet.

17 WHO HAS REVIEWED THE RESEARCH PROJECT?

The Bellberry Human Research Ethics Committee has reviewed this study in accordance with the National Statement on Ethical Conduct in Human Research (2007), incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information, or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited on 08 8361 3222.

18 FURTHER INFORMATION AND WHO TO CONTACT

If you would like any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (any adverse events or side-effects), you should contact the coordinating Investigator on 1800 866 255, who will put you directly in touch with Dr Benjamin Kwan (study doctor).
For emergency medical care, please contact emergency on 000.

THIS INFORMATION SHEET IS FOR YOU TO KEEP

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CONSENT FORM

Title	Non-invasive monitoring to translate the biometric data of participants with diabetes into blood glucose levels
Principal Investigator	Dr Thomas Telfer
Coordinating Investigator	Dr Farid Sanai
Co-investigators	Dr Benjamin Kwan, Dr Shane Cox, David Wang, Dr Mobin Nomvar, Lachlan Boyle, Arshman Sahid
Sponsor	Scimita Operations

Declaration by Participant

I am aged 18 years or older.

I have read and understand the Participant Information Sheet, or someone has read it to me in a language that.

I understand. I understand the purposes, procedures, and risks of the study, as described in the Participant Information Sheet.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in this study as described and understand that I am free to withdraw at any time during the study.

I consent to the banking of information collected about me as described in sections 13 Banking of Health Information, for use in future studies that are an extension of this study or closely related to this study. I understand that I will be given a signed copy of this document to keep.

By signing this consent form, I am agreeing to take part in the study and have understood what it involves, the time commitment required, the expectations of me as a participant, and how my data will be used.

Name of Participant (please print) _____

Signature _____ Date _____

☐ I give permission to be contacted for any future studies that may follow the current study.
☐ I give permission for the data collected during this current study to be used in subsequent studies.

Declaration by Study Investigator

I have provided the Participant with the Participant Information Sheet and have given a verbal explanation of the study, including its purpose, procedures, and risks. I believe that the Participant has understood the explanation and has been capable of providing informed consent.

Name of Study Investigator (please print)	_____
Signature _____	Date _____

NB: The Principal Investigator or an appropriate Co-investigator must provide the explanation of, and information concerning, the research project.

NB: All parties signing the consent section must date their own signature.

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PARTICIPANT WITHDRAWAL FORM

Title	Non-invasive monitoring to translate the biometric data of participants with diabetes into blood glucose levels
Principal Investigator	Dr Thomas Telfer
Coordinating Investigator	Dr Farid Sanai
Co-investigators	Dr Benjamin Kwan, Dr Shane Cox, David Wang, Dr Mobin Nomvar, Mr. Lachlan Boyle, Mr. Arshman Sahid
Sponsor	Scimita Operations

Declaration by Participant

I wish to withdraw from participation in the above study and understand that such withdrawal will not affect my routine treatment, my relationship my healthcare professionals, or my relationship with Diabetes Australia.

I understand that the medical information I have already supplied may still be reviewed and used within this study but that no new information can be reviewed.

I understand that the biometric data collected from me may still be reviewed and used within this study but that no new biometric data can be collected.

Name of Participant (please print) _____

Signature _____ Date _____

Description of circumstances for withdrawal*

* Only in the event that the participant's decision with withdraw is communicated verbally

Declaration by Study Investigator

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Investigator (please print)	_____
Signature _____	Date _____

NB: The Principal Investigator or an appropriate Co-investigator must provide the explanation of, and information concerning, withdrawal from the the research project.

NB: All parties signing the consent section must date their own signature.