KNOW LABS GLUCOSE STUDY

CONSENT TO BE A RESEARCH SUBJECT

Title of Research: Know Labs Glucose Study

Your consent to participate in this study is voluntary and is for research only. The purpose of this study is to determine the ability of the Bio-RFID sensor's ability to measure blood sugar when compared to a finger stick and/or CGM (if applicable). There are a few risks that you may experience during this study related to the finger sticks. These are: discomfort, minor bruising, and skin irritation.

Please read this consent form carefully and take your time making your decision. As your study sponsor discusses this form with you, please ask him or her to explain any words or information that you do not fully understand. This study is sponsored by Know Labs. The primary sponsor investigator is Phil Bosua. The study is being performed at the Know Labs Research Facility, located at 915 E Pine St, Seattle WA 98122. Approximately 200 people will participate in this study over a period of 12 months, or until 200 subjects have participated.

You must be fully SARS-CoV-2 vaccinated and will be required to wear a face mask during the study procedure per King County Guidelines.

You must agree that all information about medical devices, facilities, and procedures will remain confidential. No photos or recordings may be made without the explicit consent of Phil Bosua, Primary Sponsor Investigator.

You must agree to provide contact information so that Know Labs may contact you and request that you participate in a subsequent study, at your discretion. Know Labs will keep any personal information that you provide confidential and it will not be included in the results of the study. Your contact information will be housed on a "Subject Information Form", which will be a written document that you fill out.

Purpose of the Research:

This is a research study of a new type of device to measure blood sugar without sticking the finger for blood as many people with diabetes must do several times per day. However, in this research study, finger sticks will be performed as a reference comparison.

The objective of this study is to demonstrate, in human volunteer subjects, proof of concept of preliminary lab studies of the ability of Know Labs non-invasive (no needles, no finger sticks) Bio-RFID technology to accurately measure blood sugar (glucose) and changes in the blood glucose over a 2.5 to 5-hour time period.

Up to 200 subjects (male, female, or other; healthy or with type 1, type 2 diabetes mellitus or pre-diabetes) , aged 18 to 65, will have their arm placed on the Know Labs Bio-RFID sensor and their blood glucose measured for up to 120 seconds every 5 minutes. This is the experimental part of the study using the experimental device from Know Labs. The total time for a session of the study is 2.5 hours to 5 hours. Concurrent finger stick glucose measurements will be performed and recorded at each 5-minute time point. In addition, data will be collected from the CGM (Continuous Glucose Monitor) if being worn by the subject.

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

You will take a blood sugar reading using the Bio-RFID sensor every five (5) minutes. In addition, a finger stick will be performed, and the blood sugar level will be recorded. If you currently wear a continuous glucose monitor (CGM), a reading will also be taken from your current CGM.

After one half (1/2) hour of baseline measurements you will orally consume, within 5 minutes, a liquid dose of 75 grams (2.6 oz) of glucose in about 8 oz of water. Your blood glucose will then continue to be monitored as above for an additional 2 to 4.5-hour period.

If you have capillary blood glucose of greater than 300 mg/dL by finger stick, you will not be allowed to consume the oral glucose, but you may continue to participate in the study. If you have a confirmed blood glucose of greater than 450 mg/dL at any point during the study, you will be immediately excused from participation with the recommendation that you contact your health care provider as soon as possible.

The outcome measures will be the Bio-RFID sensor glucose data and the recorded blood glucose finger stick readings on all subjects in addition to the CGM glucose readings on subjects wearing a CGM (if applicable).

You may participate in the study procedure up to five (5) times with a minimum of three (3) days between study procedures.

The only risk to subjects will be the minor pain of the finger sticks and the rare occurrence of minor skin irritation/infection. These risks will be minimized by using a new lancet for each finger stick and thoroughly cleaning and drying the finger prior to the finger stick. The participant may perform their own finger sticks or if requested they can be performed by one of the sponsor investigators. The study will involve 30 to 60 finger sticks.

There will be no direct benefits for the subjects (other than minimal compensation for participation), but successful commercialization of the technology would improve the lives of all patients using finger stick glucose monitoring and has the potential of improving diabetes care as well as delaying the onset of clinical diabetes in individuals with pre-diabetes who make lifestyle changes based on this non-invasive and less expensive method of glucose monitoring.

You will be compensated up to $200 in the form of a Gift Card for your completed participation. The following is the schedule of payments based on participation level:

- If you participate at least one hour, you will be compensated $100.
- If you participate to completion of the study, you will be compensated $200.

There are no risks related to the electronic technology including the Bio-RFID sensor and spectroscopy.

Not taking part in the study is the only alternative to participation. Your participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The procedure for discontinuation is verbal communication to any of the investigators and exit from Know Labs facilities.

No personally identifiable data, or links to it, will be collected at the time of study or stored (other than this written informed consent document). The only identifiable data collected will be the informed consent documents which will be collected and securely stored by the Know Labs study site. The consent form document will not have any attached data other than your signature.

Phil Bosua, the Principal Investigator, phone 650-305-5160, address 915 E Pine St, Suite 212, Seattle WA 98122 should be contacted for any pertinent questions about **the research, technology, and study procedures**.

James H. Anderson MD, Investigator, phone 317-985-0269, address 915 E Pine St, Suite 212, Seattle WA 98122 should be contacted for any questions of **research participants' rights or in the event of research-related injury.**

Your participation may be terminated by the sponsor investigator without regard to your consent if the Sponsor closes the study early, or the research staff concludes that further participation by you is inappropriate or poses potential risks to you.

You acknowledge that you have been given the opportunity to decide to consent or not to consent to this medical device experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on your decision.

You will be given a copy of the signed and dated consent form.

_____ _____

Signature of Subject Date

_____

Printed Name of Subject

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Printed Name Person Obtaining Consent Date