INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**i-SENS, Inc./ "Method Comparison/User Evaluation of the i-SENS Self-Monitoring Blood Glucose / β-Ketone System(CareSens PRO GK)"**
Protocol Number:	**BGM-2205084**
Principal Investigator: (Study Doctor)	**Ronald Brazg, M.D.**
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Introduction

You are being asked to voluntarily participate in a medical research study that will evaluate the accuracy and usability of a Blood Glucose / β-Ketone System (CareSens PRO GK) (the study device) in untrained individuals with or without diabetes or pre-diabetes. i-SENS, Inc. and its representatives ("sponsor") are sponsoring this study and are paying the study doctor and/or the study site for their work in this study.

The purpose of this form is to help you decide if you want to be in this study.

Please read this form carefully. It may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this form to think about or discuss with family or friends before making your decision. If you sign and date this form, you are giving your permission (or consent) to be a part of this study. You can agree to take part in this study and change your mind later.

If any important new information is found during this study that may affect your wanting to continue to be part of this study, you will be told about it right away.

Confidentiality of Study Information
The information in this informed consent document is intended to help you determine whether participating in this study is right for you. You may wish to discuss this information with others for the purposes of helping you decide whether to participate in the study. You are asked to treat this information as confidential and to inform any others with whom you share this information that it is confidential. However, giving out confidential business information as described above to the media or posting it on the internet is prohibited. Please ask your study doctor for more specifics if you have a question about the nature of any particular information.

Why is this study being done?
This study is being done to assess the accuracy and usability of the study device in untrained subjects with or without diabetes or pre-diabetes. The CareSens PRO GK Meter (study device) is investigational. "Investigational" means that the device has not been approved for use by the Food and Drug Administration (FDA). The purpose of this study is to collect information that will be presented to the FDA for the purposes of approval.

The CareSens PRO GK Meter (study device) is a self-monitoring blood glucose test system (SMBG). For this study, the meter will be used by you to complete blood glucose and blood β (beta)-ketone tests using fingerstick samples. Additionally, site staff will obtain fingerstick blood samples from you in order to complete blood glucose and blood β-ketone analysis on laboratory analyzers. The results obtained by the SMBG will be compared against results collected from a laboratory analyzer. Approximately 10% (out of 350) of study participants will be naïve to SMBGs, meaning they are untrained subjects with no previous experience using a SMBG.

Participants with or without diabetes or pre-diabetes, who are 18 years of age or older will use fingerstick blood samples to test for blood glucose and β-ketone results. A blood glucose test measures the level of glucose, a type of sugar within your blood. The hormone called insulin helps your body move glucose from the bloodstream into your cells and acts as a main source of energy. The β-ketone blood test will measure ketones in the blood. Typically ketones are produced when glucose is not available to your cells as an energy source, or when there may not be enough insulin.

If you agree to join the research study, your participation will be limited to a single site visit. No follow-up is required.

How many people will take part in the study?
A minimum of 350 adult participants will be taking part in the study.

What is the investigational device and how will it be used?
The CareSens PRO GK Blood Glucose / Blood β-Ketone Monitoring system is used for the quantitative (number) measurement of the glucose/ β-ketone level in capillary (vein) whole blood as an aid in monitoring diabetes management effectively at home. The system includes the Meter, Blood Glucose Test Strips/Blood β-Ketone Test Strips, a user's manual, a quick reference guide, batteries, lancets (short needle), a lancing device and a carrying case. Two levels of control solutions (control level A and B) for glucose test and two levels of control solution (control level A and B) for β-ketone test are also associated with the test system.

All participants will be assessed for study participation based on the below inclusion and exclusion criteria:

Inclusion Criteria

- Male and females, 18 years of age and older
- People with type 1 diabetes, type 2 diabetes, pre-diabetes and no diabetes (self-reported)
- Ability to speak, read and understand English (participants must demonstrate ability to read a sentence from a page of the study device labeling instructions (user's manual) to qualify for the study)
- Willing to complete all study procedures
- Has read, understood, and signed the Informed Consent

Exclusion Criteria

- Hemophilia or any other bleeding disorder
- Works for a medical laboratory, hospital, other clinical setting, or a medical device company that involves training on or clinical use of blood glucose meters
- Physical, visual, or neurological (nerve) impairments as determined by the study doctor or study staff that would make the participant unable to perform self-testing (reason for exclusion will be clearly documented by the study doctor or study staff directly on the participant disposition form)
- A condition, which in the opinion of the study doctor or study staff, would put the participant or study conduct at risk (reason for exclusion will be clearly documented by on the participant disposition form)

If you meet the eligibility criteria, and none of the exclusion criteria, you may be asked to participate in the study.

What will happen during the study?

You will be asked to:

- Sign and date this consent form.
- Provide general demographics and medical history
- Review the study device user manual and quick reference guide
- Complete blood glucose/ β-ketone self-testing
- Review a sample meter that displays a hypoglycemia (low blood sugar)/hyperglycemia (high blood sugar) reading.
- Complete a study questionnaire

Further details about the study visit are listed below.

General Demographics and Medical History

Study staff will collect self-reported demographics, diabetes (or pre-diabetes) history, SMBG history, education background and any other information relevant to the study and to the ability to use the study device.

Blood Glucose/ β-Ketone Self-Testing

You will be provided with all the materials needed for blood glucose/ β-ketone self-testing.

1. You will be given sufficient time to review the study device user's manual and quick reference guide. No training will be provided by the trained study staff.

   Note: You should obtain your own fingertip sample, perform a test using only the study device labeling as instructions (user's manual and the quick reference guide). No other training or prompting should be provided to you and no assistance should be given from the trained study staff. You will be separated from study staff and any other study participants so that you cannot be observed or influenced by the testing technique.

2. You should wash your hands with warm water and soap, rinse and dry well.

3. You will lance (stick) your finger using a lancing device to produce a drop of blood and perform a blood glucose test with a glucose test strip on the meter. Three successful finger sticks/lances are allowed to get a meter result. The lancet should be changed after each actual fingerstick. The study staff will record the times of the meter tests, results, number of successful lances, and whether all steps were completed.

4. Immediately within 5 minutes of the first evaluable meter reading, the trained study staff will collect more blood for glucose and hematocrit (cell volume) measurement (approximately 300-350 microliters or less than 1/8 of a teaspoon) using a Tenderlett TM or tenderlett-like single use lancing device. A total of up to 3 additional fingersticks/lancings are allowed to collect blood in the collection tubes.

5. After measuring your blood glucose, you will lance your finger and perform a β-ketone test with a β-ketone test strip on the same meter. The trained study staff will record the times of the meter tests, results, number of successful lances, and mark whether all steps were completed.

6. Immediately within 5 minutes of the first evaluable meter reading, the trained study staff will collect more blood for β-ketone measurement (approximately 500-550 microliters or less than 1/8 of a teaspoon). A total of up to 3 additional fingersticks/lancings are allowed to collect blood in the collection tubes.

7. Blood for the hematocrit (cell volume) measurement can be taken from one of the fingersticks already performed. However additional blood may be needed.

8. For any meter errors, you should follow the instructions in the study device user's manual.

Study Questionnaire

After all testing is complete, you will be provided a sample meter that displays a hypoglycemia (low blood sugar)/hyperglycemia (high blood sugar) reading. Following this you will be asked to complete a usability questionnaire. This questionnaire will ask you to score or rate items related to your testing experience using the following ratings:

- 1 – Very Difficult
- 2 – Fairly Difficult
- 3 – Neither Easy nor Difficult

- 4 – Fairly Easy
- 5 – Very Easy

In total, it is estimated that the time spent at the study site will be approximately 75 minutes.

Please note the following:

- You should not make any decisions on your diabetes management (if applicable) based on the results of the investigational device.
- The meter(s) that will be used during your testing session may be used by other study participants. ALL study meters will be cleaned and decontaminated by trained study staff after each use using an approved decontamination procedure.
- You will be given a NEW lancing device and lancets and should change lancets for each fingerstick. Your lancing device will be discarded after use.

What will happen when I am finished with the study?
Your study participation ends after the single in-person study visit.

What side effects or risks can I expect from being in the study?
There may be risks to you if you are in the study. It is not known if these risks will occur, and the study staff will take appropriate actions to reduce or minimize risks. Please talk to the study staff about any questions or concerns that you may have about the procedures required for this study and their associated risks. The risks to you from participating in the study are those associated with getting blood from your finger.

Possible risks associated with the study:

- **Blood borne pathogen transmission (a blood disease)** – to reduce this risk, each study participant will receive a disinfected meter and disposable lancing device specific for their use only in the study. Participants will receive a supply of disposable lancets for use with the meter. Tenderlett or tenderlett-like lancing devices are single use only.

- **Hypoglycemia (low blood sugar), Hyperglycemia (high blood sugar) or Hyperketonemia (high ketone levels)** – There is a risk of a hypoglycemic, hyperglycemic, or hyperketonemia event during your study visit. Results from the investigational device should not be used to make any therapeutic (treatment) decisions. In the case of low blood glucose, the study staff will give you a sugary drink and food (such as orange juice and crackers) or will give you a dose of glucagon (hormone to control blood glucose) if needed, until your blood glucose returns to a safe level as judged by the study staff. In the case of high blood glucose, the staff will talk to you about your blood glucose result, and you will be encouraged to report this to the primary care doctor you see for your diabetes/general health.

- **Finger stick –** the following risks are unlikely but possible:
    - Pain – worsening pain that interferes with activity
    - Redness (erythema) – bright redness spreading across the area of the fingerstick
    - Bruising
    - Discomfort
    - Local irritation or infection – bright redness or skin darkening spreading across the area with warmness and/or swelling, and/or red streaking
    - Fainting

- Nerve Injury – numbness or shooting pain
- Continued Bleeding

You should report any problems to the study staff or study doctor.

In addition, there may be a risk of loss of confidentiality, or other risks to you (or the embryo or fetus, if you are pregnant) which are currently unforeseeable.

Are there benefits to taking part in the study?
There is no direct benefit from participating in this study. A potential benefit associated with the study may be the sense of well-being gained by contributing to the development of improved or new blood glucose/ β-ketone monitoring systems, which may be beneficial to people with diabetes.

What are alternative treatments or choices if I do not agree to participate?
Your alternative is not providing blood samples or participating in the study.

What happens if I want to stop the study?

Your taking part in this study is entirely voluntary. You may refuse to take part in the study, or you may stop your participation in the study at any time. You may do so without a penalty or loss of benefits to which you are otherwise entitled. If you decide to stop your participation in this study, you must inform the study doctor or study staff immediately. The study doctor may also withdraw you from the study if in his or her medical judgement it is not advisable for you to continue.

Your participation may also be terminated for one of the following reasons:

- Adverse Event (unexpected medical problem)
- Illness
- Non-compliance with study requirements
- Other reasons, in the option of the study doctor

What are the costs of taking part in this study?
There is no anticipated cost/charge to you or a third-party carrier (your insurance) for participating in the study.

Will I be paid for taking part in this study?
You will be compensated for your participation as outlined below:

If you complete the study, you will receive compensation of $100.

You will be paid within 30 days after your study participation has ended.

What happens if I am injured because I took part in this study?
If you are injured, please seek medical help. If you follow the directions of the study doctor and study staff and you are physically injured due to any study device or procedure properly given under the plan for this study, the sponsor will pay the medical expenses for the treatment of that injury which are not covered by your medical insurance, by a government program, or by any other third party.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Whom to contact about this study?
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Study Doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the Study Doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participant. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00064057.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Will my medical information be kept private?
The study doctor and study staff will handle your personal health information in a confidential manner.

By signing and dating this authorization, you give permission ("authorization") for the uses and disclosures of your personal health information in the following ways.

- Your original medical records (which may contain your full name or other information that may directly identify you) may be shared with or viewed by the following to ensure the quality of the study conduct and study data:
  - The sponsor of the study and its representatives "sponsor,"
  - The regulatory authorities in this country (such as the FDA) and in other countries, and
  - The ethical review board overseeing this study, Advarra IRB).
- Your study data (information collected for the study which only identifies you by a code and not your full name or other information that may directly identify you) may be shared with or viewed by:
  - The sponsor and their business partners (including those in other countries),
    - When the sponsor shares any data outside of this country, the sponsor will respect the terms of this data privacy statement even if other countries may have privacy laws that do not provide the same protections,
    - The sponsor will only share your study data with their business partners, only if they need the information as a part of this work with the sponsor. The business partners must sign a contract that requires it to protect your study data in the same way as the sponsor.
  - The regulatory authorities in this country and in other countries,
  - The ethical review board overseeing this study, and
  - The doctors at other institutions participating in the study.

- The sponsor will use the study data:
  - To support the study purposes described in the consent document,
  - To assess the accuracy and usability of the study device in untrained subjects with or without diabetes or pre-diabetes,
  - To improve the design of future studies.
- Study data that does not directly identify you may be published.

Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by your study doctor to these other parties.

You have the right to see and copy your personal health information related to the research study. However, you may not be able to review some of the study data until after the study has been completed to ensure the scientific integrity of the study.

Your authorization for the uses and disclosures of your personal health information does not have an expiration date. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document.

You may only participate in the study if you provide authorization. You may cancel your authorization for the uses and disclosures of your personal health information at any time by providing written notice to the study doctor at the address listed on page 1 of this form. If you cancel your authorization:

- The study doctor and study staff will only use or disclose some of your personal health information if it is needed to confirm the accuracy of the study data.
- The sponsor will still use study data that was collected before you cancelled your authorization.
- You will no longer be able to participate in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Study Participant

_____ _____

Signature of Study Participant Date

Study Participant Information and Consent Form Signature Page

To become a part of this study you must sign and date this page.

Only sign and date this consent after:

- You have read all the information in the consent form, and you have had time to think about it.All your questions have been answered to your satisfaction.

You voluntarily agree to be part of this research study, and to do the following:

- Follow the study procedures, and
- Provide necessary information to the study doctor, study nurses, or other study staff members, as requested, and

You may freely choose to stop being a part of this study at any time. You will receive a copy of this signed and dated Consent Form to keep.

For Study Participant To Complete

Signature of Study Participant	Date (Study Participant must personally date)

Study Participant Name (print or type)

Individual Conducting Informed Consent Discussion to Complete

I have explained the study (such as the purpose, risks, benefits, and the procedures) to the study participant before the study participant voluntarily agreed to participate.

Name of Individual Conducting Informed Consent Discussion (print or type)

Signature of Individual Conducting Informed Consent Discussion	Date (Individual Conducting Informed Consent Discussion must personally date)