MINIMALLY-INVASIVE BLOOD GLUCOSE TESTING IN TYPICALLY-DEVELOPING ADULTS

1. SCOPE

To allow the measurement of blood glucose levels in participants, thereby facilitating research relating to either changing or constant blood glucose levels.

The procedure will involve taking a very small blood sample from participants (a single drop of blood) using a procedure originally devised for self-testing by diabetics. This will be obtained using a (fresh, single-use) lancet, which will then be disposed of. Each lancet has three different depth settings to allow for maximum comfort depending on how callous an individual's skin is. The sample will be taken for use with a hand-held blood glucose monitor, for which the manufacturers' instructions for use should be followed. This will allow an accurate, readily available and minimally invasive reading of an individual's blood glucose to be obtained.

The Medisana MediTouch blood glucose monitor and Safe-T-Pro Plus Lancet Devices are to be used with this procedure.

The manufacturers' instructions for the Medisana MediTouch blood glucose monitor are attached. However, please note that the lancet referred to in the instructions is not the same type that will be used. The instructions refer to a non-disposable lancing device for personal use, whereas the method proposed here would use disposable, single-use lancets that retract once they have been used to prevent further use. These single use lancets can be obtained from Roche Accu-Check suppliers, such as Mistry Medical Supplies and are called Safe-T-Pro Plus Lancet Devices.

Provided that correct procedure is followed, there should be no risk to participants, researchers or any other people.

This approved procedure will not cover the performance of any diagnoses made on the basis of the blood glucose measurements. They are to be obtained and used purely for research purposes. In any instance that the researcher feels there is cause for concern (i.e. the blood glucose level is higher than the normal range), then the procedure for this should be followed, and the participant should be encouraged to contact their GP. This procedure is detailed below under the 'results of the test' section.

2. TRAINING OF RESEARCH STAFF

Researchers carrying out the procedure will not need to undergo formal training. However, it is important that they familiarise themselves with the instruction manual for the specific blood glucose monitor that they are using.

In addition, the 'User's Guide' included with both the blood glucose monitor and the lancets should also be read by researchers as this provides information on how to ensure proper use of the machine and to minimise discomfort of participants.

3. METHODS FOR RECRUITING PARTICIPANTS

As the participant group covered by this approved procedure is not specialised in any way, their recruitment should be in line with guidelines set forth by the Central University Research Ethics Committee (CUREC), and any guidelines specific to individual departments and lab groups. Recruitment should not deviate from these approved procedures and guidelines. In view of the focus of the test on blood glucose, individuals will be asked if they are diabetic, but will not necessarily be excluded on these grounds.

4. INFORMATION PROVIDED TO PARTICIPANTS

Participants should be given both a written and a verbal explanation of what the blood glucose testing involves. They should be made aware of the procedure at the time of recruitment and be given ample opportunity to ask questions. The procedure outlined in the 'Procedure' section below will be explained to them.

In addition to the procedure being explained to them, the limitations of the researcher's capabilities should also be explained. Therefore, it should be made clear that this is not a diagnostic test and that no health advice can be given by the researcher. At the beginning of the testing session it should be clearly explained that if, for whatever reason, the results give cause for concern then the participant would be encouraged to contact their GP. It will also be explained that in this instance the researcher can provide the participant with a letter explaining the results of the tests that were done so that they are able to pass this information on to their GP if they wish.

The Information Sheet should be written in simple and non-patronising language. Most word-processing packages provide readability statistics for a document, and one should aim for a 12-year-old (Year 7) reading level for adults.

Please refer to the **Information Sheet and template letter associated with this Approved Procedure.**

5. CONSENT OF PARTICIPANTS

Once the participants have had the procedure clearly explained to them and been given the opportunity to answer questions, written consent must be obtained specifically for the blood glucose testing component of the experiment.

Please refer to the **Consent Form associated with this Approved Procedure.**

Please also see CUREC's current guidance on the informed consent process.

6. PROCEDURE

The researcher would carry out the following steps:

a) Put on gloves and clean the test site (normally the side of a fingertip, avoiding thumb and index finger) by asking participants to wash their hands with warm soapy water and to dry them thoroughly. Cleaning is important to prevent contamination which could affect the result. Encourage participant to keep hands warm prior to sampling as this improves blood flow.

b) Ensure the participant is seated comfortably or lying down before the procedure.

c) Place a new glucose-testing strip into the electronic meter according to manufacturer's instructions.
d) Prepare a new single-use disposable lancet.
e) Hang the arm below the heart for 30 seconds to increase blood flow.
f) Puncture the site with the lancing device and then gently squeeze the finger in a downward motion to obtain a large enough drop of blood to cover the test strip.
g) Place blood on testing strip and complete measurements with the monitor according to manufacturer's instructions, ensuring that the results are recorded in a logbook.
h) Compress lanced area with a tissue or gauze until bleeding stops and apply a plaster if necessary.
i) Promptly dispose of the lancet in a sharps bin and safely dispose of any waste.

7. COMPENSATION

Consideration should be given to how and when participants are told about any recompense. Participant information sheets and recruitment materials should state that recompense will be made so that potential participants are not discouraged from participating by the associated costs. As a general rule, recruitment material should not state the value. However, if this is necessary (e.g. it is a requirement of a third-party recruiter), advertisements must not emphasise the value of the payment (for example, through the use of formatting). Further guidance is available within CUREC's Best Practice Guidance 05 on Payments and incentives in research.

8. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE

There are a few potential risks involved in this testing of blood glucose, which the procedure is designed to minimise. There is the risk of the researcher contracting a blood-borne disease carried by the participant and so to prevent this, disposable latex or nitrile gloves must be worn at all times and disposed of in a safe and secure manner. Risk of infection to participants is also a possibility. To minimise this risk, participants are asked to thoroughly wash their hands to ensure the test site is clean, a fresh disposable lancet is used each time a sample is taken, and a fresh test strip is also used each time a sample is taken. In addition, tissues and plasters will be provided to protect the point of puncture from the possibility of infection. Ensure the participant is seating or lying comfortably before the procedure to minimise risk of injury in the event of a vasovagal (fainting) response.

9. COMMUNICATION OF RESULTS

Participants should be informed of the results of the blood glucose test. They will be told that the normal range of blood glucose levels is between 4 and 8 mmol/l.

Should their blood glucose levels fall outside these norms, the participants will be informed. This is the most beneficial course of action to take because the health implications of unusual blood glucose levels can be serious (for example, diabetes), and can be treated and managed effectively by medication. Therefore, the participant will be informed if his/her result is outside the normal range indicating the potential health implications and suggesting that they visit their GP as soon as possible. Such participants will be given a standard letter stating the results to be shown to their GP. If the blood sugar is out of range (low or high) and the participant also feels or appears unwell, they should seek urgent medical attention, and should be advised to dial 111.

10. DATA PROTECTION

All data collected about an individual will be obtained directly from the individual themselves and with their consent. It will subsequently be stored in accordance with the UK General Data Protection Regulation (GDPR). Blood samples collected will be disposed of with the test strip, into which they are absorbed.

11. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
1.0	Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
1.1	Updated hyperlinks for new CUREC website	1.0
1.2	Updated for General Data Protection Regulation (GDPR)	1.1
1.3	Updated to improve accessibility	1.2
2.0	Quinquennial Review and administrative revisions	1.3