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 a participant'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 a participant'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

Potential participants will be identified by one of the methods outlined on the CUREC application. When a potential participant registers interest, further information (prepared using the associated template information sheet) will be sent, together with details as to how to confirm they would like to take part.

In view of the focus of the test on blood glucose, participants 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

Written consent will be obtained from all participants using the **Consent Form associated with this Approved Procedure.**

Written consent will be obtained from all participants on the day of the first session, following a suitable (at least 24 hour) period during which they will have had an opportunity to read the Information Sheet and discuss their participation with others and with the researchers. An experienced researcher will answer all and any questions before consent is obtained. Consent will be taken by a member of the research team who has appropriate training, as confirmed by the Principal Investigator. Written consent must be obtained specifically for the blood glucose testing component of the study. Participants will be reminded that they are able to change their mind and withdraw from the study at any point without penalty. Vulnerable populations or participants who are unable to provide informed consent in English are not covered by this Approved Procedure.

Copies of the signed consent forms will be provided to the participants along with the information sheet. The originals, along with the TMS safety questionnaires administered before every session, will be kept in the files of the researchers.

Please also see CUREC's 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 MANAGEMENT AND PROTECTION

The research must be conducted in accordance with the University's Policy on the Management of Data Supporting Research Outputs; CUREC's Best Practice Guidance 09 on Data collection, protection and management; and Research Data Oxford's guidance on data backup, storage and security.

Blood samples collected will be disposed of with the test strip, into which they are absorbed.

Participants' informed consent must be obtained for participation in the study, which includes the collection, storage and retention of all data related to the study. Directly identifiable personal information held by the research team (such as contact details, consent forms and screening forms, which include name or other identifiers) must be held securely - either in paper format in lockable filing cabinets with access only by the University researchers, or in a password-protected database, on an encrypted machine or on a protected server. These should be servers provided by the University where the risks and access have been professionally managed. Other servers will require security assessment by University Information Security. Other research data (e.g., EEG files, behavioural reaction time files, questionnaires) must be labelled with a code number rather than a name or initials, and accessed via a password- and firewall-protected server.

The keys linking personal details to the codes used to label other research data may be kept in paper format in lockable filing cabinets with access only by the researchers, or in a password protected spreadsheet on University approved servers. The keys should be kept separately from other study data. Such keys should be destroyed as soon as no longer needed, as should other personal data (with due regard to University and other guidelines on data retention, e.g. of consent forms).

Contact details may be retained after the end of the research where the participant agrees to be contacted for future studies. These should be held separately from the study data, and a copy of the consent form retained as evidence of agreement to be contacted. For participants who do not wish to be contacted in the future, contact details will be destroyed as soon as possible after completion of their research participation. Personal and research data may be viewed by regulatory bodies and designated individuals within the University of Oxford for the purposes of monitoring and auditing the research with the written consent of the participant.

Anonymised data may be shared with other research institutions, including researchers outside of the UK and the EU, for use in other and future research studies. For detail on anonymisation, please refer to the Information Commissioner's Office (ICO) Code of Practice –'Anonymisation: managing data protection risk', especially Appendix 2 and Annex 1.

Where data has been anonymised (all identifying information removed, including any linkage document), there is no limit as to how long this may be retained by the researchers. However, the period of retention should be stated on participant information.

Sharing of Data

Research teams will be encouraged to make their data available for reuse and validation. In all cases, the data will be shared as openly as possible and as closed as necessary in order to protect the privacy of participants. Online repositories will be assessed by research teams for their appropriateness with regard to:

- the required treatment and de-identification of unique brain and biometric data in line with UK GDPR;
- control of how the data are accessed and re-used, including terms to protect the ongoing privacy of participants;
- required attribution of the data to the originating research team, the University and funding bodies;
- management of data withdrawal requests made by participants.

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
2.1	Administrative revisions Complete update of data management section – text approved by CUREC Nov 2021	2.0