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 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, it is recommended that they visit the website of Accu-Check where they may find a leaflet entitled ‘Taking the Sting out of Testing’ (https://www.accuchek.co.uk/gb/customerservice/Leaflets-and-Resources.html). This leaflet provides tips on how to make sure the process causes minimal discomfort.

In addition, the ‘User’s Guide’ included with both the blood glucose monitor and the lancets should also be read by experimenters 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 the tests that were done so that they are able to pass this information on to their GP if they wish.

The Information Sheet is written in simple but 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.

Current guidance on the informed consent process, together with a template consent form can be found at: http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent
6. PROCEDURE
The researcher would carry out the following steps:
   a) Put on gloves and clean the test site (normally the topside of a finger) by asking participants to wash their hands with warm soapy water and to dry them thoroughly.
   b) Place a new glucose-testing strip into the electronic meter according to manufacturer’s instructions.
   c) Prepare a new single-use disposable lancet.
   d) Hang the arm below the heart for 30 seconds to increase blood flow, and massage the finger as this will help make the pricking less painful.
   e) 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.
   f) 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.
   g) Compress lanced area with a tissue until bleeding stops and apply a plaster if necessary.
   h) Dispose of the lancet in a sharps bin.

7. FINANCIAL AND OTHER REWARDS TO PARTICIPANTS
These should be kept in line with the level of reward given for otherwise comparable studies that do not involve taking blood. Any food or drink based rewards should not be given until the end of the study as these may affect the results of the blood glucose test.

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 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.

9. COMMUNICATION OF RESULTS
Participants will 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.

10. DATA PROTECTION ISSUES

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 Data Protection Act (1998). Blood samples collected will be disposed of in a safe and hygienic manner, compliant with the requirements of the Human Tissue Act, and will carry no information that makes identification of the individual participant possible.

11. CHANGE HISTORY

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