The POET Study (***Use of point of care testing for monitoring and management of long-term conditions: A validation and feasibility study***).

Name of Researcher: Dr David Webb

Participant Information Sheet

INTRODUCTION

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve, so please take time to read this information sheet carefully and discuss with others if you wish. If there is any part of this information sheet that you do not understand, or require further information on, please contact us and we will be happy to answer any questions you have.

WHAT IS THE PURPOSE OF THIS STUDY?

Currently there is more focus on increasing the use of technology in healthcare. This can be in ways such as online video consultations, electronic medical records, and the use of other online tools to manage long-term conditions like diabetes. Through the use of technology in healthcare settings, we hope to improve patient experiences and reduce the amount of time people need to attend healthcare settings for appointments.

For people with diabetes and other long-term conditions, collecting and measuring blood samples remains an important part of the management of their conditions. Blood sample collection is usually performed during a visit to the healthcare setting and is performed face to face. However, we may be able to use technology to allow blood sampling to be done at people's homes safely and effectively.

The main aim of this study is to see if blood samples collected outside of the healthcare setting (i.e., at home) using finger prick methods (also known as Point of Care Testing, or POCT) are as accurate as blood samples obtained through traditional face to face methods, such as venepuncture (through the vein). If Point of Care Testing is found to be as reliable as traditional methods, this may become a useful way to provide care to people with long-term conditions without the need for them to attend appointments, which in turn may be more cost effective for the NHS and may reduce waiting times for appointments.

WHY HAVE I BEEN INVITED TO TAKE PART?

You have been invited to take part in this study because you are an individual who is attending an out-patient clinic for routine blood assessments, and you are aged 18 years or older.

DO I HAVE TO TAKE PART?

No, your participation is voluntary and deciding not to take part will not affect any care that you receive. Please ask if you need more time to make up your mind, or if you need to know more or want to ask any questions. If you need more time, you can take a copy of the information sheet with you, and contact us if you have more questions, or when you are ready to participate. If you do decide to take part in the study, you can still stop taking part at any time by contacting a member of the study team using the details at the end of this information sheet. However, data and samples already collected will still be used, unless you specify otherwise.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If after reading this Information Sheet, you are interested in taking part in the study, you will be asked to sign a consent form. You will be asked to provide a blood sample at this appointment and to provide some information about yourself and your conditions. There are no other visits or assessments required. You will also be given the opportunity to consent to the second phase of this study which involves obtaining a blood sample at home and posting this back to the Leicester Royal Infirmary, along with a short survey about the experience of home blood testing. Finally, a sample number of participants will be invited to take part in an interview lasting no more than 1 hour. The interview will be conducted remotely via telephone or online platform such as Teams, or Zoom. Expressing an interest in these additional parts does not mean that you have committed to them and you can change your mind without this affecting your participation in the main part of the study. The study has been divided into two parts:

- Blood sample collection in a healthcare setting (Validation Phase)
- Blood sample collection at home (Feasibility phase)

Validation Phase – Blood samples obtained in the healthcare setting

This phase of the study is being conducted at hospitals and up to 30 GP practices. If you agree to take part in the Validation Phase, a member of the study team will check that you are eligible to take part. We will collect brief information about your medical history and your demographic information such as your age, race and gender. If you have diabetes, we will also ask if you are familiar with testing for glucose at home. Finally, we will collect blood samples from you to measure the following:

- HbA1c
- Potassium
- Sodium
- Urea
- Creatinine
- Total cholesterol

- Low Density Lipoprotein (LDL)- cholesterol
- High Density Lipoprotein (HDL) cholesterol
- Triglyceride (TG)
- ALT (Alanine Aminotransferase)
- CRP
- TSH (Thyroid Stimulating Hormone)

Some of these form part of your routine care for which you are attending your appointment, whereas some of these are collected specifically for the purposes of this research.

Samples will be collected using 3 methods:

Through the vein (venepuncture) – we will collect 10ml (less than a tablespoon) of blood while you are having any routine blood samples done.

Finger prick (capillary blood sample) – this method will involve using the finger prick method to collect a few drops of blood into a small tube.

Dried blood spot – this method will involve a few drops of blood that are blotted onto absorbent paper and allowed to dry. This will be done through the same finger prick as for capillary samples, but if we are unable to collect enough drops, this may involve a second finger prick. This means that there will be a maximum of two finger prick samples during this study phase.

Feasibility Phase – Blood samples obtained at home

If you took part in the validation phase of the study and are living with a long-term condition such as diabetes, with your permission, you may be further invited to take part in the next stage of the study, called the Feasibility Phase. If you consent to participate in the Feasibility Phase, you will be asked to collect blood samples on only one occasion at home using the same finger prick methods detailed above. You will receive a testing kit in the post, containing everything needed to take the samples at home and a pre-paid jiffy bag to post the blood samples back to the laboratory at the Leicester Royal Infirmary. Participants will also be asked to fill in a short satisfaction survey about their experience of performing the blood sampling at home. The completed surveys will be returned to the Leicester Diabetes Centre in a separate pre-paid envelope. Full instructions on how to collect the blood samples and complete the survey will be included in the test kits.

Not all individuals who express an interest in the Feasibility Phase of the study will be invited to take part. This is because we are hoping to recruit 420 participants into the Validation Phase, but only 100 participants into the Feasibility Phase.

Finally, up to 20 participants of the Feasibility Phase will be invited to take part in an interview lasting no more than 1 hour. The interview is to explore and find out your views and

experiences of taking part in this study. The interview will be conducted remotely via an online platform such as Teams, or Zoom, and will be audio recorded only. The camera will be turned off. The recordings of the interviews will then be shared with a third party who will write up the interviews in a process called 'transcription'. All identifiable information and details are removed during the process of writing up, meaning that you cannot be recognised. This also means that once the interview has been written up, you will not be able to withdraw your data from this part of the study. Recordings of the interview will be deleted once they have been written up.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

There is no direct benefit to you from taking part in this study. However, by taking part in this study you are contributing to our understanding of the accuracy of collecting blood samples outside of the traditional healthcare setting.

If we find that this is a safe and accurate way to collect blood samples, then it may be a useful way to change how we provide this type of service and management to patients in the future. This may be more convenient for patients instead of coming to hospital or going to their doctor for routine bloods and may reduce some of the burden within the NHS.

WHAT ARE THE POSSIBLE RISKS OF ME TAKING PART IN THIS STUDY?

We do not anticipate there will be any risks associated in your taking part in this study. The study involves one blood test and a maximum of four finger pricks which carry a low risk of having any unpleasant effects apart from mild discomfort from finger pricks and occasionally slight bruising, scarring, swelling or some temporary discomfort or pain which can occur at the site of venepuncture. This can be easily treated with painkillers such as paracetamol.

WILL MY PARTICIPATION IN THE STUDY BE CONFIDENTIAL?

We will be using information from you, your GP and your medical records for this research project. This information will include your name, initials, date of birth, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead and anyone that we work with will be bound by rules of confidentiality too. With your data, we will make sure we are compliant with General Data Protection Regulations (GDPR) and follow the Data Protection Act (2018). We will keep all information safe and secure.

Once we have finished the study, we will keep some of the data so we can check results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the Validation Phase and Feasibility Phase of the study at any time, without giving a reason, but we will keep information about you that we already have, unless you specify otherwise.
- As part of the Feasibility Phase, once your interview transcript has been written up, it will not be possible to withdraw your transcript from the study. As detailed above, because we remove all identifiable information and use a code instead, once we have written up the transcripts of the interviews, we will not be able to identify which transcript belongs to you.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Your contact details will be stored on the Leicester Diabetes Volunteer Database, and you may be contacted about future research opportunities.
- Your research data (only) will be transferred to the University of Leicester once the study has finished.
- Direct quotes from the interviews may be used in study reports, or research publications. We will remove all identifiable information prior to these activities.
- At the end of the study, with your permission, we would like to keep your research data (with your unique study code on it) for use in future research. We may share your data with other individuals for the purpose of future research. This might include other researchers, our collaborators and/or commercial organisations both within and outside of the UK and EU subject to there being official contracts in place to allow the transfer. If we share your data, your unique study code will be removed which means that your data will be anonymous, and you cannot be identified from it.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to the University's Data Protection Officer, dpo@le.ac.uk.

WHAT WILL HAPPEN TO SAMPLES COLLECTED FROM ME?

We will test all the different types of blood samples in the same way and we will be using the results of these tests to find out whether collecting blood samples at home produces the same results as when blood samples are collected within the healthcare setting. This will show us whether the different sampling methods are as good and as accurate as one another. Most samples will be tested at the Leicester Royal Infirmary laboratory. For some of the measures that we are interested in, the blood samples will need to be tested at the Van Geest Biomarker Facility (University of Leicester). Where samples are processed outside of the NHS, these samples will be shared in a coded format, and any identifiable data will be removed prior to transfer so that these individuals will not be able to identify you.

At the end of the study, with your permission, we would like to keep your remaining blood samples (with your unique study code, visit number and collection time point on them) for use in future ethically-approved research. We may share your samples with other individuals for the purpose of future research. This might include other researchers, our collaborators and/or commercial organisations both within and outside of the UK and EU subject to there being official contracts in place to allow the transfer. If we share your samples, your unique study code, the visit number and collection time will be removed which means that your samples will be anonymous, and you cannot be identified from them.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Once the study is finished, we will be speaking at conferences about our research and writing articles for medical journals and other publications. This may include the use of quotations if you take part in the interview described above. Additionally, the data collected from this study may also be used in part or in whole, for the writing of educational projects such as a Master's degree or a PhD. You will not be able to be identified from any of the publications or presentations. A summary of the results will be made available to all participants.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

The study is being funded by the NHIR as part of the M3 Research Programme and is being managed by researchers at the Leicester Diabetes Centre. The study is sponsored by the University of Leicester.

WHO HAS REVIEWED THIS STUDY?

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee, who work to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and approved by the independent Research Ethics Committee >>insert name of REC and reference ID issued by REC<<. In addition, the Research Ethics Committee will observe the progress and results of this study. Review has also been undertaken by independent experts during its development.

WHAT IF I AM HARMED BY THE STUDY?

It is very unlikely that you will be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, please contact the study team using the contact details at the end of this information sheet. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact the Patient Advice and Liaison Service (PALS) by email (pals@uhl-tr.nhs.uk) or Freephone (0808 1788337).

In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence, then you may have grounds for legal action for compensation against the University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

HOW CAN I FIND OUT MORE?

The study team will be very pleased to answer your questions and provide more information about the study. If you require any further information or you would like to discuss the study further, please contact:

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