

6. Are there any risks or benefits in taking part ?

As with blood sample collection in routine clinical care, collecting a finger-prick sample may result in short term slight pain and/or bruising.

The results we share with you and your doctor may in some cases lead to a change in your treatment and/or the advice that you are given by your doctor. The potential for improved longer term health outcomes should be far greater than any possible concerns that may result from a recommended change to diabetes management and/or treatment.

By taking part in this research you could play an important role in helping to improve the diagnosis and management of patients with diabetes across the UK.

7. How will we use information about you?

In this research study we will need to use information from you, from your medical records and from your clinical care team. This information will include your NHS number, your name, your date of birth and your 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. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the 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 study at any time, without giving a reason, but we will keep information about you that we already have.

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. If you choose to be re-contacted for future studies, we will transfer your data to the Peninsula Research Bank (PRB) for long term management, once this study is completed.

You can find out more about the PRB here: <https://exetercrfnihr.org/about/exeter-10000-prb/>

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

- At www.hra.nhs.uk/information-about-patients/
- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By emailing the research team: rduh.diabetesresearch@nhs.net
- By emailing the Sponsor's data protection officer: rduh.dpo@nhs.net

8. What will happen to the results of this study ?

The results will be published in appropriate medical and scientific journals and presented at conferences both in the UK and abroad. A summary of the results, outlining the key findings of the study will also be made available to all study participants. Data sharing with other researchers is important to optimise the use of good quality research data and to support policy and other decision-making. Therefore, all anonymised research data will be included in the final dataset and stored in an approved data repository.

9. Who to contact if you would like further advice or have a complaint

Please contact the study team or the Sponsor using the contact details in section 4 of this leaflet. However, if you have concerns or complaints arising from your experience of participating in this study which you do not wish to discuss with people directly involved in the research, the Patient Advice & Liaison Service, Tel: 01392 402093 or Email: rduh.pals-eastern@nhs.net can provide independent advice. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the Royal Devon University Healthcare NHS Foundation Trust who the research sponsor. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Complaints Team, Email: rduh.complaints-eastern@nhs.net. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against the **Royal Devon** but you may have to pay your legal costs.

ARC-T1D

A research study to test whether we can use home finger-prick blood samples to confirm Type 1 diabetes in adults

We are inviting you to take part because:

- You were diagnosed with diabetes more than 3 years ago and your diabetes is treated with insulin.
- You are registered with a diabetes clinical team within the Royal Devon University Healthcare NHS Foundation Trust.

Taking part takes about 20 minutes:

- Collect a finger-prick blood sample at home & send it to the hospital for a C-peptide test (a measure of how much insulin your body is making).
- The blood test result, with information about what it means, will be sent to you and your diabetes doctor.

- Before you decide whether to take part, it is important to understand why the research is being done and what it will involve.
- Please take the time to read this study information carefully & discuss with family & friends if you wish.
- You are free to decide if you want to take part & deciding not to will have no impact on your NHS care.
- Please ask us if anything is not clear or if you would like more information.

**Funded by Medical Research Council IAA Impact Visionary Fund
Supported In-Kind by Trajan Scientific Europe Ltd**

1. Why are we doing this study?

It is not always easy to diagnose Type 1 diabetes (T1D) in adults because the symptoms can overlap with Type 2 diabetes (T2D) and misclassification of diabetes type can occur. This matters as T2D cases misclassified as having T1D could potentially receive a lifetime of unnecessary insulin treatment.

Whether someone needs treating as T1D can be confirmed by measuring their insulin levels, using a blood test called C-peptide. That test should be done at least 3 years after diabetes diagnosis as closer to diagnosis, insulin levels in T1D and T2D can overlap.

A study in Scotland measured C-peptide in a clinic of patients treated as T1D showing around 1 in 15 of cases were misclassified. As a result, all patients in Scotland with a long –standing diagnosis of T1D now have C-peptide measured and that is likely to be recommended across the UK. In addition to the extra burden on clinical staff to collect those blood samples, not all UK laboratories are set up for C-peptide tests so testing all patients will be very challenging.

The team in Exeter have validated a method for measuring insulin levels (using the C-peptide test) in finger-prick blood samples which can be collected by patients at home and posted to a hospital laboratory. Clinic visits are not needed and testing can be done at a hospital laboratory where C-peptide testing is already routinely available.

This study will run for 12 months and will assess whether this approach is workable and useful by requesting & testing finger-prick blood samples from a general population of adults treated as T1D at a hospital diabetes clinic. To properly assess this method of sample collection we will look at the number of samples returned, the number of patients choosing not to take part, the staff time required as well as the number of patients with a C-peptide result that indicates the type of diabetes is not T1D.

2. Why have you been invited to take part in this study ?

You are invited because you were diagnosed with diabetes at least 3 years ago. Your diabetes is treated with insulin, you are currently 18 years of age or over and you are registered with the diabetes clinical care team at the Royal Devon University Healthcare NHS Foundation Trust.

3. Who is organising this study ?

It is led by Dr Nick Thomas, Prof Angus Jones and Prof Tim McDonald and the diabetes research team at the Royal Devon University Healthcare NHS Foundation Trust & University of Exeter Medical School.

It is Sponsored by the Royal Devon University Healthcare NHS Foundation Trust.

It is supported by the National Institute for Health & Care Research (NIHR) through the Exeter Biomedical Research Centre and Exeter Clinical Research Facility.

It has been reviewed by:

The Peninsula Research Bank Patient & Public Involvement Groups

The Health Research Authority and independent National Research Ethics Committee (North West—Greater Manchester East) under IRAS reference number 338864

It is funded by: Medical Research Council IAA Impact Visionary Fund

It has In-Kind Support from Trajan Scientific Europe Ltd who are providing the Neoteryx Mitra blood collection devices.

4. Who can you contact for more information ?

If you would like to discuss the study in more detail with the research team please contact:

Study Team Email: rduh.diabetesresearch@nhs.net

Telephone: 01392-408181

Principle Investigator Email: n.thomas3@nhs.net

The study Sponsor is the Royal Devon University Healthcare NHS Foundation Trust. Email: rduh.research-eastern@nhs.net

5. What will you need to do if you take part?

Read the information in your study pack, **Ask** questions and **Discuss** with others

- Please read this information leaflet, the consent form & the sample collection instructions.
- Follow the links provided if you require more detailed information.
- Contact the research team if you have any questions about taking part.:

Email: rduh.diabetesresearch@nhs.net

Telephone: 01392-408181

Please feel free to discuss the study with family and friends before making a decision.

- **You are free to choose whether to take part and deciding not to will have no impact on your standard NHS care.**

You Decide To Take Part

- Complete the consent form
- Collect your sample, following the instructions provided.
- Add the date & time of collection to the sample label.
- Place your sample & consent form into the pack provided.
- Pop the pack in the post as soon as possible.

You Decide NOT To Take Part

Please return your unused study pack in the pre-paid envelope provided.

We Test Your Sample & Report The Result

- Your sample will be tested at the NHS clinical laboratory at the Royal Devon University Healthcare NHS Foundation Trust.
- The C-peptide result will be reported to you and your diabetes clinical care team with information about what the result means.
- Any discussion about possible change of diabetes treatment or management will be led by your diabetes consultant. Changes to the management of your diabetes will not be made without your agreement.
- You will be given the option to provide feedback on taking part in the study and the result you received