8. Optional Extras

Samples that you have donated during this study, and samples left over from routine care tests, may be discarded or gifted to help future research. You will be given the option to donate the samples and data collected for this study to a research bank to be used in future research. This research bank is based in Exeter and is managed by a steering committee of healthcare professionals, academics and members of the public who have also participated in research. The committee will ensure that samples and data are used anonymously on studies that they feel are ethically appropriate. These studies may be in the UK or abroad and may involve collaboration with companies, but samples and data will not be sold for profit, not shared with non-research organisations and not used in animal research or reproductive cloning. Your DNA may be used in future studies, but will not be actively screened for genes predictive of disease. You will also be given the opportunity to join a local research database to be contacted about future studies local to you. If you do not wish to be contacted for future studies, all personal information held by the research team will be deleted within 12 months of the study finishing.

9. What will I be asked to agree to?

Thank you for reading this information. If you are happy to participate, you will be asked to consent to the following statements at your first research visit in the presence of a member of the research team.

I confirm that :

- I have been given a study information leaflet.
- I have had the opportunity to ask questions and have had these answered satisfactorily.

I am happy :

- to donate blood and urine samples collected during this study, and for DNA to be extracted from my blood sample.
- tor samples leftover from my routine clinical care to be used for diabetes research tests.
- to provide the research team with information about my diabetes and other information relevant to my participation in the study.
- to allow the research team to contact my clinicians/GP about my participation in the study and to provide them with clinical results relevant to my care.

I understand that:

- my participation is voluntary and that I may withdraw at any time without giving any reason and without my clinical care being affected.
- members of the research team will have access to sections of my medical notes that are relevant to my taking part in this research.
- individuals from regulatory authorities will have access to data collected during the study, and relevant sections of my medical notes, for monitoring and audit purposes.

Optional consent statements

- I am happy to complete the optional study questionnaires.
- I am happy to gift samples and data, collected during this study, and as part of my routine diabetes care, to the Peninsula Research Bank in Exeter to be used for future research. I understand that these studies will be approved by a steering committee and my samples will not be used for any of the following: Sold for profit, used in animal research, used in research into the termination of pregnancy or reproductive cloning, screened for markers predictive of disease (e.g. Huntingdon's). My samples may be provided anonymously to researchers from the UK and abroad including academic organisations and commercial companies.
- I agree that information held by the NHS and in my medical records may be used to follow up on my future health status.
- I am happy to be contacted by the research team about participating in other future studies and for NHS-based staff to access my medical records to check my eligibility for future research.

Before you make a decision about participating in this study, you may want to discuss the project with your GP or family members. The Patient Advice & Liaison Service (01392 402093) can provide independent advice on participating in research and can help if you have any queries or complaints about your research experience.

10. How to contact us:

If you have any questions about this study, please contact us on:

Telephone: **01392 408181** Email: **rde-tr.DiabetesResearch@nhs.net**

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StartRight

Getting the right classification and treatment from diagnosis of diabetes

You could take part in this research study if you were:

- **Diagnosed with diabetes in the last 12 months**
- **Aged 18 years or over at diagnosis**

- **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 the following information carefully.**
- **You are free to decide if you want to take part in this research study.**
- **You can decide to stop taking part in the study at any time without giving a reason.**
- **Please ask us if anything is not clear or if you would like more information.**

Contents

This Research Project Is Funded By

The National Institute for Health Research and Diabetes UK

1. Why are we doing this study?

There are three main forms of diabetes: Type 1 diabetes, Type 2 diabetes and genetic diabetes. The treatment for each is very different because they have different causes.

It is not always easy for doctors to be able to say for certain what kind of diabetes a person has. Getting the right diagnosis is important to know what treatment will be most effective; for example patients with Type 1 diabetes need insulin, whereas most patients with type 2 diabetes may be effectively treated without insulin.

The purpose of this research is to determine whether blood tests can help us improve treatment by identifying which patients have Type 1 diabetes, and will need very early insulin treatment, and which patients are unlikely to need insulin treatment at diagnosis. These tests include antibodies against the cells that make insulin (often seen in Type 1 diabetes), and a new test which assesses genetic risk of diabetes.

2. Why have I been invited to participate?

We are inviting you because you have been diagnosed with diabetes during the last 12 months and you were 18 years of age or over at the time of your diagnosis. By participating you may help us discover whether early testing of blood samples can improve diabetes diagnosis and treatment.

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

As with your standard diabetes care, providing blood samples may be uncomfortable, but the blood collection will be carried out by experienced staff.
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.

4. Will my participation be kept confidential?

If you join the study, you will be given a unique study ID number. All information that is collected about you will be held on a password-protected computer. Access to this data and samples will be available to the research team only.
Tests your doctor would often request, such as blood sugar (HbA1c), will be copied to your GP and/or hospital diabetes team to avoid unnecessary repeat blood tests. We will share results from antibody tests at the first visit, and insulin secretion tests at 3 years, with yourself and your doctor. We will not share other results routinely, as we need to do the study to find out if other research tests may be helpful.
All samples and research data will be stored securely using numerical barcodes and researchers involved in data analysis will only have access to anonymised data. At the end of the study anonymised research data will be kept for a minimum of 5 years

5. Who is organising this study?

This project is being run locally by the Clinical Research Facility at the Royal Devon and Exeter Hospital. It is funded by the National Institute for Health Research (the research arm of the NHS) and Diabetes UK (the leading UK charity for people affected by diabetes), and is centrally coordinated by the NIHR Exeter Clinical Research Facility . The project has been reviewed by the Peninsula Research Bank PPI group at the Exeter CRF and by the National Research Ethics Committee (South West—Exeter) under IRAS reference number 203567

6. What will I need to do if I take part?

The study involves 4 appointments (2 face to face appointments and 2 by phone, email, post or in person). Details of what will happen at each visit are shown below. At some recruiting sites it may be possible for the researcher to see you in your own home, at your GP surgery or local hospital if it is difficult for you to travel to the research centre.

Initial Discussion

- Discussion of eligibility and detailed study overview
- Agree convenient date and time of visit 1.

Baseline Visit 1

45 to 60 minutes

- Written consent.
- Clinical data collection including height, weight and blood pressure
- Blood and urine samples
- Diabetes data including diagnosis, treatment & hypoglycaemia
- Optional wellbeing and resilience questionnaires.

1 year and 2 years after Visit 1

1 year & 2 year follow-up by phone, email, post or in person. (Visits 2 & 3)

15 to 20 minutes

- Diabetes treatment & hypoglycaemia update
- Details of any hospital admissions since last visit
- Urine sample (collected at home and posted to research centre for analysis)
- Collection of results (such as blood sugar) from your clinical records (hospital or GP).

3 years after Visit 1

3 year follow-up Visit 4

30 minutes

- Review of the study details and consent.
- Repeat of clinical data collected at visit 1
- Blood and urine samples
- Diabetes treatment & hypoglycaemia update
- Optional wellbeing and resilience questionnaires.

The anonymous results and outcome of the research will be shared with you once the whole study has ended and all analysis is complete.

7. Samples and Tests

You will be asked for blood and urine samples during the study. Blood tests that may be important for your clinical care (such as blood glucose, kidney function or cholesterol) will be analysed by your local NHS laboratory and copied to your GP. Research blood and urine samples will be sent to the lead site in Exeter for study specific tests. The results of those tests will be sent to you and your GP direct from the central research team in Exeter. Remaining samples will be anonymised (the samples will be stored using a code without your name or other personal details) and stored for further specialist tests. Genetic material (DNA) will be extracted and stored anonymously.
At some sites, we will ask your permission to use leftover samples from your routine diabetes care for research tests (e.g. testing for levels of insulin on the sample provided for your routine HbA1c check). Access to samples or information related to samples is restricted to members of the research team only.