5. Samples and Tests

You will be asked for blood samples during the study. Blood tests that may be important for your clinical care will be analysed by your local NHS laboratory and copied to your GP. Research blood samples will be sent to the lead site in Exeter for study specific tests. Remaining samples will be anonymised (using a unique code without your name or personal details) and stored for further specialist tests. Genetic material (DNA) will be extracted. 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. At the end of the study anonymised research samples will be kept for a minimum of 5 years or, with your permission, transferred to a research biobank (please also see Section 8). Samples not transferred to a research bank will be disposed of in accordance with the Human Tissue Act (2004) Code of Practice 5 and the local NHS waste management procedures.

6. 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. By taking part in research you could play an important role in helping patients diagnosed with diabetes in the future.

7. Who is organising this study?

This project is being run locally by [*insert* local *research centre*]. It is funded by JDRF, the Type 1 diabetes charity, and the Wellcome Trust. It is centrally coordinated by the NIHR Exeter Clinical Research Facility and forms part of a PhD project for one of the investigators.The project has been reviewed by the Exeter Diabetes PPI Group, the Health Research Authority and an independent National Research Ethics Committee (Wales Rec 7) under IRAS reference number 261315

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 rare disease. You will also be given the opportunity to join a research database to be contacted about future studies local to you.

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

The results of the study 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 provided to study participants. We will write our reports in a way that no-one can work out that you took part in the study.

10. What will happen if I don't want to carry on with the study?

You are free to withdraw at any time and without giving a reason. Choosing not to take part in the study or withdrawing at a later date will have no impact on your standard NHS care. 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.

11. Who can I contact for further information/complaints?

If you would like to discuss this study further with a member of the study team, please contact your local research team on:

Telephone: 07833 236542 (research nurse) OR 01392 408184 (Study team answerphone)

Email: rde-tr.DiabetesResearch@nhs.net

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 and Exeter NHS Foundation Trust who are acting as the research sponsor. Details about this are available from the research team. 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 Patient Liaison Manager 01392 402093 or email: rde-tr.PALS@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 RD&E NHS Foundation Trust but you may have to pay your legal costs.

Sponsored by the Royal Devon and Exeter NHS Foundation Trust

University of Exeter Medical School | Royal Devon and Exeter NHS Foundation Trust

DROPLeT

A research study to understand the progression of Type 1 diabetes in adults

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

- **Diagnosed with Type 1 diabetes in the last 100 days**
- **Aged 18 years or over at the time of diabetes diagnosis**
- **Receiving Insulin Treatment**

- **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.**

This research project is funded by:

JDRF, the Type 1 diabetes charity, and the Wellcome Trust

1. Why are we doing this study?

Type 1 diabetes occurs when the body's immune system destroys the cells that make insulin. It has often been thought of as a disease of young people, but recent work has shown that about half of cases occur after age 30. There has been little research into Type 1 diabetes in this age group - in part because, with increasing age, Type 2 diabetes is much more common.

A focus of research in Type 1 diabetes in recent years has been to develop early treatments to slow the progression of the disease and preserve a person's own insulin secretion. It has been shown that preserving a persons own insulin secretion leads to less variable blood sugar levels, and lower risk of both hypoglycaemia (low blood glucose) and diabetes complications. These studies have usually focussed on young adults under age 30 (or in some cases children). A key reason that older adults have not been included is that it has been thought that Type 1 diabetes in older adults is a milder disease and does not progress rapidly. Our research has suggested this is not true, and that older adults diagnosed with Type 1 diabetes have rapid progression similar to that seen in younger adults. If this is the case, older adults could be included in these important studies of treatments to slow diabetes progression. We would also like to find out if a home blood spot test can provide an accurate measure of a person's insulin secretion, and therefore replace meal tests performed at a research centre. If we can measure insulin secretion without needing frequent research centre visits this will significantly reduce study burden for future participants.

2. Why have I been invited to participate?

We are inviting you because you have been diagnosed with Type 1 diabetes within the last 100 days, you were 18 years of age or over at the time of your diagnosis and you are receiving insulin treatment. This study is aiming to determine the rate of decline in insulin production in adults diagnosed with type 1 diabetes. By participating you may help us to find out if older adults (aged over 30) with type 1 diabetes have similar rates of progression compared to young adults. (aged under 30).

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 (*insert local contact number*) can provide independent advice on participating in research

3. 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 for this research project. This information will include your NHS number, your name, your date of birth and your contact details which will be shared with the Chief Investigator's central study team in Exeter. 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. (please also see section 10).

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records & your clinical care team. If you do not want this to happen, tell us and we will stop.

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.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by asking one of the research team (see section 11 for contact details).

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

The study takes 1 year to complete and everything can be done at home. On 3 occasions we will ask you to fast overnight (not to eat or drink anything except water for 8 hours) and collect finger prick blood samples both before and 90 minutes after drinking a liquid meal (a bit like a milk shake). We will also ask you to collect finger prick blood samples at home on 2 other occasions during the year. We will provide special packaging for you to post the samples to the central laboratory in Exeter. We will ask you to wear a continuous glucose monitor (CGM) &, in some people, we would like to be able to collect fingerpick samples up to weekly (these are optional extras). **Please see the flow diagram opposite which provides more detailed information about taking part in this study.**

In the future, it may be possible to offer you a face to face visit at your local research centre when a contribution towards your travel costs will be offered & a light breakfast will be provided at the end of the visit.

Initial Discussion

- Discussion of eligibility and detailed study overview
- Agree convenient date and time of visit 1 (a minimum of 24 hours after initial discussion).

Remote visit at home 1.5 to 2 hours

- Detailed discussion about the study procedures and verbal consent (by phone or video call)
- Clinical data collection including diabetes diagnosis, treatment, height and weight.
- A liquid meal replacement, capillary (finger prick) blood sample collection kits, a DNA swab kit & 2 copies of your verbal consent record will be sent to you with detailed instructions & contact details for experienced diabetes researchers who will be available to answer any questions during the home procedure.
- You will be asked to check the verbal consent record & confirm it with your signature.
- Following overnight fast, collect finger prick blood samples before drinking the liquid meal and at 90 minutes after drinking the liquid meal. You will need to collect drops of blood onto a special card & into a small tube by using a finger-prick test (similar to how you would check your blood sugar levels).
- Collect a DNA sample using the mouth swab kit provided
- Post the samples with your signed record of consent to the central site in Exeter in the pack provided.
- You will be asked to wear a continuous glucose monitor, called a freestyle libre pro, a tiny glucose sensor which will be placed in your upper arm and will remain in place for 14 days to measure your daily glucose. After this time, the sensor can be removed and returned by post to the research team.
- You will be asked to collect blood spots onto a card on 3 or 7 days following your liquid meal test and return them to Exeter.
- At some sites you may be asked to wear an activity monitor on your wrist (like a watch) for 14 days & then post it back to the central site in Exeter with your CGM.

OR

OR

If face to face research visits are possible, you may be offered a similar appointment at your local research centre. That appointment will be longer & additional blood samples will be collected:

Visit to local research centre 2.5 to 3 hours

- A cannula (a small plastic tube) will be inserted into a vein for blood tests, and removed at the end of the visit.
- After drinking the liquid meal a series of blood samples from the cannula in your vein & finger prick samples will be collected over 2 hours.

12-14 weeks after first visit

Home blood spots

- Home blood spot tests posted to the central research laboratory for analysis.

24-26 weeks after first visit

Remote visit at home 1.5 to 2 hours

- Review of the study details and confirm participation.
- Repeat of clinical data collection, meal test & blood sampling.
- You will be asked to wear a continuous glucose monitor and to do a home blood spot test on 3 or 7 days following your research visit.
- You may be asked to wear an activity monitor on your wrist for 14 days.

36-38 weeks after first visit

Home blood spots

- Home blood spot tests posted to the central research laboratory for analysis.

48-52 weeks after first visit

Remote visit at home 1.5 to 2 hours

- Review of the study details and confirm participation.
- Repeat of clinical data collection, meal test and blood sampling.
- You will be asked to wear a continuous glucose monitor and asked to do a home blood spot test on 3 or 7 days following your research visit.
- You may be asked to wear an activity monitor on your wrist for 14 days