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PARTICIPANT INFORMATION SHEET (11-15 years)

UK Islet Autoantibody Registry (UKIAb)

Invitation to Take Part in a Research Study

We would like to invite you to join our research study. Before you decide, it's important to understand why we are doing this research and what it will mean for you. Please take some time to read this, and feel free to talk to others if you like. If there’s anything you don’t understand or if you have questions, you can always ask us. If you

What is a research study?

This is something we do when we want to find out something new. We are doing research with children like you so that we can learn more about children at risk of type 1 diabetes.

Study summary

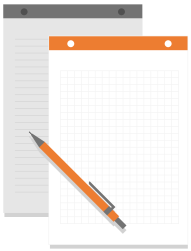
Type 1 diabetes (T1D) is a condition that lasts for life. It happens when the immune system attacks the pancreas, the part of the body that makes insulin. Insulin is a chemical that helps control your blood sugar levels. People with T1D need to replace insulin for their whole life, by either injections or using an insulin pump.

People with a higher chance of developing T1D often have markers in their blood called T1D autoantibodies. If someone has two or more of these markers, there’s an 80-90% chance they will get T1D within 15 years, and most of them will develop T1D at some point in their life. If someone has only one marker, the risk is much lower, about 15%. It’s now possible to test for these markers even before someone shows signs of T1D.

We are creating a registry (a database) of children and adults with T1D autoantibodies.

If you decide to take part, we will ask your permission to collect information about your health every year.

What is the purpose of the study?



We want to create a registry of people with T1D autoantibodies to help us learn more about the experience of being at risk for T1D. It will also allow us to offer new treatments or opportunities to be part of research studies that are trying to delay or stop T1D from happening. We also want to know what kind of support people at risk of T1D need and whether they use NHS services more because they are worried about getting T1D.

Why have I been invited?

You have been invited because you have one or more T1D autoantibodies in your blood. We are trying to recruit about 350 children and adults (aged 6 months to 70 years old) who have one or more of these markers.

Do I have to take part?

No, taking part is completely voluntary. You can choose whether you want to join or not. Even if you decide to join, you can change your mind and leave the study any time, without having to explain why. If you choose not to take part or decide to leave later, it won't affect any medical care you receive, or your legal rights.

What if I say 'yes' and my parents say 'no'? What if I say 'no' and my parents say 'yes'?

We do our best to make sure both you and your parents are happy with your decision. You can make the decision, and if you do decide you do not want to take part that is OK, and we will respect your wishes.

What will happen if I take part?

If you decide to join the study:

1. We will ask your parent/guardian to sign a consent form and we will ask you to sign an assent form, and you'll get a copy of them.
2. If your T1D autoantibody test was done more than a year ago, or as part of your normal care with your doctor, we may need to test you again to confirm your autoantibody status.
3. The T1D autoantibody test is a simple blood test done by pricking your finger. We'll send you a kit so you can do this at home. We'll need your name and address to send the kit.

4. Once the test is confirmed, a member of the research team will contact you and your parent/guardian to confirm that you have been enrolled. We'll also let your GP (family doctor) know.
5. At the start of the study, we'll collect some information about you, like your medical and family history, your test results, and contact details. We'll use this to follow up with you about your health and to tell you and your parents/guardians about future research studies.
6. We will check in with you once a year with a short survey about your health and use of health services.
7. We will ask your permission to look at your health information from the NHS every year for as long as you are part of the study, the 'data linkage' study This study uses the information you give us about your health and links it with the information in your medical records, to answer questions about people at risk for T1D.

What else should I consider?

- You cannot join the registry if you are currently taking insulin.
- You can still join the registry even if you are part of another research study.

By joining, you are agreeing to:

- Let us use your information to access and use details from your NHS records (optional).
- Let us share your information with other researchers, but only if they have special approval and training to use it (optional).
- Allow us to contact you about other research studies or new treatments in the future (optional).

Are there any downsides to taking part in the study?

The main risk is the finger prick test to confirm your T1D autoantibody status. It's a small prick on your finger that you do at home with a kit we send you. You can ask your parent or guardian to help you. It might make your finger a little red and sore for a short time.

You may have worries about possibly developing T1D in the future. There is more information about T1D on our website www.ukiab.org, or you can contact our study team using the details at the end of this sheet.

Will joining the study help me?

By taking part in this registry, you may get the chance to be part of new research studies or treatments that could help delay or prevent T1D. We will use the results to improve how we support people who are at risk of T1D in the future.

Will my doctor be told?

Yes, we will ask for your permission to let your GP know that you are part of the registry and share your test results.

Will my information be kept private?

Yes, all your information will be kept private. When you join the study, we will give you a special number and this will be put on the information and data we collect from you. This data will be stored safely and we will not use your name, so researchers will not know who you are.

We will only use your name, date of birth, and address if we need to link it to your NHS records or contact you about the study. Your information will be kept safe and secure at the University of Oxford and in a trusted database. No-one outside the research team will know who you are unless it's important for your safety. If something comes up that means you or someone else might be at risk of harm, we may have to tell someone, but we will talk to you first.

What will happen to my information?

There are laws about how we use ('process') the information ('data') we collect from you for this research. The law says that we have to tell you what the reason is for collecting and using the information – for research like this, it is 'a task in the public interest'. That means we are doing this research because we think it is important for everyone. The University of Oxford is in charge of the research (the 'sponsor') and in charge of the information we collect about you (known as the 'Data Controller'), that means we are responsible for making sure we take care of your information and use it properly.

If you would like to know more about how we use the information we have collected about you, you can find out here: https://compliance.web.ox.ac.uk/individual-rights. We have also given more information about this to your parent or guardian and you can talk about it with them if you want to.

Will I be paid?

There is no payment for joining the registry.

What will happen to my blood samples?

If you take the test to confirm your autoantibody status, we will keep the sample only long enough to check the result. After that, we will destroy any leftover sample.

What happens if I don't want to continue?

You can stop being part of the registry anytime without having to give a reason. If you leave, we will still use any information we've already collected but won't ask you for any more.

What if I am worried about something?

If you have any concerns about any part of the study, you can speak to your parents or person looking after you, or you can contact us by email: ukiab@ndm.ox.ac.uk .

What will happen when the study stops?

After the study ends, the results will be shared so that everyone knows what we have found. None of this information will identify you or your family.

Has anyone else checked this study is ok to do?

Yes, before any research study is allowed to happen, it has to be reviewed by a group of people called an Ethics Committee. They look at studies carefully and make sure they are ok to do.

Questions?

Thank you for reading about our study. If you have any questions, we'd love to hear from you.

You or your parents/carers can contact us at ukiab@ndm.ox.ac.uk. Or telephone the study team on 07765 932065.

Thank you for considering taking part in our study.