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# PARTICIPANT INFORMATION SHEET
# (Parent/Guardian)

## UK Islet Autoantibody Registry (UKIAb Registry)

You and your child are invited to take part in our research study. It is entirely voluntary and, before you decide whether to take part, we would like to give you some information on what it would involve. You can take part in some or all of the studies. Please take some time to read this information and discuss it with friends or relatives. If anything is unclear, our contact details are at the end of this form. If you need a copy of this information sheet in another language, please contact the UKIAb Registry team using the details at the end.

### What is the purpose of the registry?

Type 1 diabetes (T1D) is a life-long condition where the immune system destroys part of the body (the pancreas) which makes the chemical, insulin. Insulin is needed to control blood sugar levels. Treatment involves life-long insulin replacement by injection or insulin pump.

The risk of developing T1D increases with presence of markers in the blood called islet autoantibodies (IAb). Children with two or more IAb have an 80-90% chance of developing T1D within 15 years. It is almost certain that they will develop the condition in their lifetime. Children with only one IAb have a much lower risk of developing T1D (around 15%). Less is understood about the natural history of being IAb positive in adults, and we hope this study will help us understand more.

We would like to establish a registry of children and adults with T1D IAb in order to:

- Keep in contact with people with IAb – we will tell you about any treatments (if available) that could delay or prevent T1D, or opportunities for your child to take part in research
- Understand what it is like knowing your child is at increased risk of T1D in order to help develop better resources to support people
- Collect data on how fast T1D develops
- Understand whether people with IAb use NHS services more than others; for example, due to being anxious about developing T1D

### Why have we been invited?

- You have been invited because a test has shown that your child has one or more IAb, or your child has taken part in a T1D related study (e.g. ADDRESS-2)
- We are aiming to recruit around 350 children and adults (aged 6 months – 70 years)

## Do we have to take part?

- No, taking part is entirely voluntary. If you decide your child can take part but later change your mind, you can withdraw at any time and without giving a reason
- If you decline to take part or take part and then later withdraw, this will not affect your child's legal rights, or any clinical care they may be receiving

## What will happen if we decide to take part?

In addition to the registry, you can also consent to take part in one or both of the following sub-studies:

- ***Data Linkage***
- ***The interview study***

### *The Registry*

We will ask you to complete a consent form (either online or on paper) confirming your child's participation. If you need help, one of our study nurses can go through the form with you.

If your child is aged 8 years or older, and you confirm that it's appropriate, we can provide a study information sheet for your child to confirm their willingness to take part (assent). If your child is showing clear refusal, then we would not proceed with enrolling them into the registry.

If your child is aged 13-15 and not aware of their T1D IAb status, we would encourage you to discuss it with them prior to enrolling them into the registry, so that they can have an active role in the decision to join, and provide permission (assent) if they wish.

Your child will need a confirmatory IAb test if:

- Your child has been tested in clinical care (by their GP or in hospital) or have been part of the ADDRESS-2 study.
- We will offer a repeat T1D IAb test. If their IAb test was more than 12 months ago
- The IAb test is done via a finger prick blood test at home, using a kit we provide you. We will need to collect your name and address in order to send the kit to you, and your child's initials will be entered on to the study screening log. Please see the 'What will happen to my child's data?' for more information

- Once the results of the test have been confirmed, you will be notified of the test result and that your child has successfully joined the registry. We will notify your child's GP of their test result and their enrolment.
- We will collect some information from you at the start of the study, such as medical and family history, your child's IAb test result, how you found out about the study, and your contact details so that we can follow up with you about your child's health status and contact you about future research.
- We will contact you once a year to complete a brief questionnaire about your child's health service usage. If your child turns 16 while enrolled in the study, we will contact them to seek their consent to continue with the registry. We will also contact you to alert you to the need for reconsent. If they do not respond after all reasonable attempts have been made to contact them, they will be withdrawn from the registry, and will no longer be contacted about new studies or treatment. We

would like to continue collecting information about their health from central NHS records. If you or your child do not want this to happen, tell us and we will stop.

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## What should I consider?

By taking part, you are agreeing to:

- Allow us to use your child's details to access and use the information in their routinely collected NHS records (optional)
- Allow us to share de-identified (pseudonymous) data with other researchers if they have scientific and ethical approval for the questions that they would like to answer with the information, and have the right training (optional)
- Be contacted about future research studies and/or treatments (optional)
- Please note that your child can join the registry without agreeing to the above

## Are there any possible disadvantages or risks from taking part?

If your child needs to take the test to confirm their IAb result, this will require a finger prick blood sample. This can be done at home with a kit we will send you. There may be a small amount of redness and temporary soreness where the blood was taken from the finger.

We will contact you via email or letter to confirm the results of your child's IAb test, and will also inform your GP.

We understand that you may have worries about your child's health and their potential to develop T1D, and there are links to further resources on the study website www.ukiab.org or you can talk to one of our team.

## What are the possible benefits of taking part?

- By taking part, your child may be offered the chance to take part in research studies and be offered new treatments to delay or prevent T1D, if they become available.
- We will contact you if new studies or treatments become available for your child, and a list of studies currently accepting participants can be found on the UKIAb Registry website, in the 'Find out more' section: www.ukiab.org

## Will my child's General Practitioner (GP) be informed of their participation?

Yes, we will notify your GP of your child's participation in the registry and their T1D IAb results (if they are tested as part of the registry), this forms part of the study consent and is required in order for your child to take part in the study. Notifying your GP will ensure that they are aware of your child's antibody status and increased risk of developing T1D.

## Will taking part in the study be kept confidential?

Yes. All study records and samples will be identified only by a unique study code. We will only use names, date of birth, postcode and NHS numbers where this is necessary to link to your child's NHS records and contact you about the study. Information that can identify your child will be held securely by the University of Oxford.

## Will I be reimbursed for taking part?

- There are no payments for taking part in the registry.

## What will happen to the samples my child gives?

- If your child provides a blood sample to confirm their IAb result, their sample and any information recorded about them will be assigned a study code that is used, instead of their name or other identifiers, to help keep their information confidential. The sample will be sent to the Alistair Williams laboratory in Bristol, for analysis.
- If your child takes a test to confirm their IAb result, any sample remaining will be destroyed once we have the result of the test.

## What will happen to my child's data?

Data protection regulation requires that we state the legal basis for processing information about your child. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. The University of Oxford and the Trusted Research Environment (TRE) provider (if you consent to data linkage) are the data controllers, and are responsible for looking after your child's information and using it properly.

Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or an audit of the study to ensure that the research is complying with applicable regulations.

Further information about how health and care researchers use information from patients, service users and other participants in research can be found on the Health Research Authority website: www.hra.nhs/uk/patientdataandresearch

### *Future research*

If you agree to your/your child's details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.

We will also seek your consent to use your child's de-identified data in future ethically-approved research.

Data released to researchers may only be used and shared for scientific and health-related research. Scientific and health-related research includes basic research, applied research, and commercially and/or publicly funded/sponsored research aimed at developing new ways to diagnose, treat and prevent health problems. Commercially sponsored health care research is funded and sponsored by private sector organisations, for example pharmaceutical companies, and can take place in NHS or non-NHS settings.

Their de-identified data may also be transferred to recipients in countries outside of the UK/EU. In these countries, the level of data protection may be lower. In order to ensure the protection and confidentiality of the de-identified data, appropriate protection and security measures are taken by the data provider and data recipient.

Requests for access to the data generated through the registry will be controlled by the Data Access Committee, which is comprised of members of the Study Management, Study Steering Committee

(which provides independent oversight) and the Patient and Public Involvement Groups. We will only consider projects that have appropriate ethical approval.

***Data management***

We will store any research documents with personal information, such as consent forms, as part of the research record, securely at the University of Oxford until 3 years after the youngest subject reaches 18 years old or 5 years after the end of the study, whichever is longer.
We will keep any other identifiable information about you/you child for 12 months after the study has finished.

The study team will use your/your child's name, NHS number, home address and contact details to contact you about the research study and to oversee the quality of the study.

Your study data will be assigned a unique study number. Only our research team will have access to the data and it will be stored securely at the University of Oxford, and the TRE.

Data protection regulation provides you with control over your personal data and how it is used. However, when you agree to your information being used in research, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights
You can find out more about how we use your information by contacting ukiab@ndm.ox.ac.uk

## What will happen if we don't want to carry on with the study?

Your child can withdraw from the registry at any time without needing to provide any explanation. If you and your child do decide to withdraw, we will continue to use any data we have already collected up until that point, as outlined in this information sheet.

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

Withdrawal from the registry will not affect your child's legal rights, or any medical care your child may be receiving.

***Data Linkage***

We will seek your consent to follow up your child's health status and health service use via central NHS registers. For more information about the use of routine data in research, please see these videos created by the Centre for Trials Research in Cardiff:

https://www.youtube.com/watch?v=OTSXVSqIF9E

https://www.youtube.com/watch?v=f5JUjT_oh48

Data will be collected on a regular basis into the future, unless you tell us to stop. This is optional. Please see the section 'What will happen to my child's data?' for more information.

## Will taking part in the study be kept confidential?

The data held in a Trusted Research Environment (TRE) will be de-identified and held securely with

the appropriate information governance and security accreditation for the purposes of the study.

## What will happen to my child's data?

With your consent, we will be using information from you, your child's hospital/GP records, research data (if appropriate) and central NHS registries (including England, Scotland, Wales and Northern Ireland) in order to undertake this study to be able to assess the impact of screening on NHS services. We will use the minimum personally-identifiable information possible.

The data will be stored on secure servers at the University of Oxford. Linkage will occur by sending identifiers to NHS bodies, then sending de-identified data to a Secure Data Environment (SDE)/Trusted Research Environment (TRE) with robust security and information governance controls. NHS bodies will return the relevant datasets for linkage to the SDE/TRE without the identifiers, and these will then be linked to the de-identified registry dataset by a common linkage field. Once the data is in the TRE and linked it will be held in a non-identifiable format until a time that the data are no longer required for research purposes. It is not possible to identify individuals once the data is in the TRE and linked due to the double encryption process.
Access to this linked dataset within the TRE will be permitted for approved projects submitted by researchers from outside the central study team.

## *Interviews*

We will be inviting some people who are eligible to join the registry, and parents of children in the registry, to take part in an interview study to understand what it is like for inidivuals and families to live with a positive IAb result, and be at risk of T1D. We want to understand the experience of of testing positive for IAb and the information and support needs, so we can offer better care and support to people in the future.
We will approach 12-15 parents/guardians of a child in the registry and 12-15 IAb positive adults for an interview, as well as 12-15 children aged 8 and over, if appropriate.

Agreeing to be approached for an interview is optional and will not affect your child's ability to take part in the Registry. If you decide you would like to be approached for a parent/guardian interview, this can be confirmed on the consent form. The team in Edinburgh, who will conduct the interviews, will then select individuals to invite to interview, so that we have a range of parent and participant experiences.

If you have consented and are invited to take part in the interview, you would be interviewed over the phone or via a video call at a time and date which is most convenient to you.

- Your interview would be conducted by an experienced and independent interviewer based at Edinburgh University, and recorded using an encrypted digital recorder.
- The interview is expected to take around 45 minutes, but may last longer.
- You can decline to answer any of the questions if you wish to do so, and you can stop the interview at any time without giving any reason.

### Will taking part in the study be kept confidential?

For the study interviews, nobody will be told whether or not you have taken part. All information that you supply to us during the course of the research (e.g., your contact details to arrange an interview) will be kept strictly confidential and will be used solely to contact you on a one-to-one basis about the interview study.

The interview would be audio-recorded using an encrypted digital recorder and sent securely to a professional external company (First Class Secretarial) to be typed up into a transcript. The transcription company will sign a confidentiality agreement with the University of Edinburgh before any recordings are shared with them.

All information that could potentially identify participants will be removed at the point of transcription. Interview audio recordings will be destroyed as soon as the transcripts have been checked. The professional transcription company will be held to the same levels of confidentiality as the researchers. Nothing that could identify you will be kept in the typed-up transcript. When findings from the study are written up, we may use your words as examples attached to a pseudonym but in a way where it will not be possible to identify you.

The data collected as part of the interview study, will be shared and stored with the University of Oxford, as sponsor for the research. The data will be stored on secure servers and access will be restricted to members of the study team.

### What are the possible benefits of taking part?

- For the interview, we will be using the findings to improve the information and support given to people and their families who receive a positive T1D IAb result, and to shape care policy in the future.

### Are there any possible disadvantages or risks from taking part?

- We understand that you may find it difficult talking about living with the risk of T1D. Our trained researchers can signpost you to help and support, or can direct you to one of our team if you would like to discuss your concerns further.

### Will I be reimbursed for taking part?

- If you take part in the interview study, we will offer you a £40 high street voucher, to compensate you for your time, at the end of your interview. If you require any financial support to enable you to take part e.g. mobile phone vouchers, please contact our researchers, as we may be able to help.

## General Considerations

### What happens at the end of the study?

After the study ends the overall results will be shared. We will present anonymised results at scientific meetings and the findings will be written into a research paper for publication.

Study updates and publications can be found on the registry website: www.ukiab.org

## What if there is a problem?

If you have a concern about any aspect of this study, please contact the study team: ukiab@ndm.ox.ac.uk They will do their best to answer your questions.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you or your child suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, and you or your child are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study; contact Dr Rachel Besser rachel.besser@well.ox.ac.uk or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

## How have patients and the public been involved in this study?

- We have involved members of the public in the design of the study, including those who have had diverse screening experiences.
- To develop this research question, we have involved parents of children who have been identified as having positive IAb, some of whom are living with T1D themselves.
- For more information on taking part in research, see: https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-take-part-in-a-study.html

## Who is organising and funding the study?

This study is organised by the University of Oxford and funded by Diabetes UK. The study is also supported by the National Institute for Health Research (NIHR) and Oxford Biomedical Research Centre (BRC).

## Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by South Central - Berkshire Research Ethics Committee.

## Participation in future research

If you agree to allow us to contact you for future research, your contact details would be held separately from this study on a secure database, which will be password-protected and accessible only by our research team at the Centre for Human Genetics, University of Oxford.
Any contact will come from our research team first, and agreeing to be contacted does not mean you have to take part. We can also remove these details from this register at any time if you wish.

## Further information and contact details

If you have any queries, we'd love to hear from you. Please contact the UKIAb Registry team via email: ukiab@ndm.ox.ac.uk

## Thank you for reading about our study