



UNIVERSITY OF  
BIRMINGHAM



## ELSA-1 (Early Surveillance for Auto-immune diabetes)

### Professional Stakeholder’s information leaflet

#### 1) Invitation

As a professional stakeholder (for example academic doctor, clinician in the field of type 1 diabetes, general practitioner, or school teacher), you are invited to take part in the ELSA-1 study co-production workshops. Joining the study is your choice. Before you decide, we would like to tell you about why we are doing the ELSA-1 study and what it would involve for you. Please read through this leaflet and you can find out more details on our website. Please feel free to talk to us and ask us any questions.

#### 2) ELSA-1 Co-production Summary

The ELSA study is looking to explore and trial a type 1 diabetes (T1D) testing and monitoring programme in children.

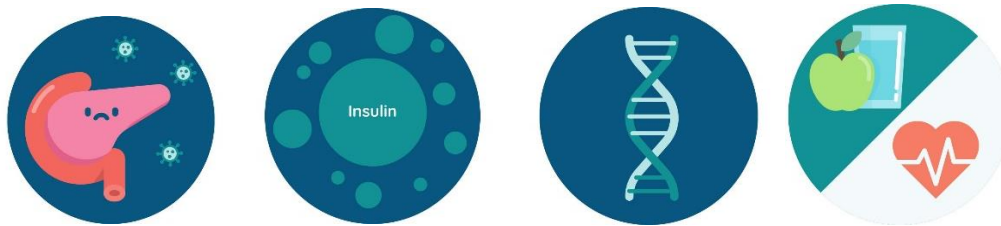
In the ELSA-1 study, we will interview families and professional stakeholders to understand how acceptable a testing and monitoring T1D programme would be. We also want to learn how we can reduce barriers to uptake and implementation.

In the ELSA-2 study, we will use the insights from the ELSA-1 study to adapt and trial our T1D testing and monitoring programme.



#### 3) What is type 1 diabetes and why is it important?

Type 1 diabetes (T1D) is a life long illness, that often starts in childhood. T1D is an auto-immune process arising due to genetic and environmental factors. Children with T1D need insulin injections for life and are at risk of other health issues.



Around the world, research studies are finding children who are at high risk, so that we can offer treatment to help delay T1D.

#### **4) Why are we doing the ELSA-1 study and co-production work?**

If we find children who are very likely to get T1D in the future, we can observe them more closely in a monitoring programme. This means we can help prevent development of Diabetic Ketoacidosis. Also, these children could go into other research trials, to test treatments to delay the start of T1D.

ELSA-1 will also help us understand what families and professional stakeholders think and feel about a testing and monitoring programme for T1D in children. The ELSA-1 co-production work will also help us address any barriers to delivery of the ELSA-2 study. These insights will therefore help us adapt the ELSA-2 study to make it more acceptable and reduce barriers to uptake.

ELSA-2 is the T1D testing and monitoring part of the ELSA study, which involves a simple blood sample to test children for T1D and then monitors high risk children over time.

#### **5) What does the ELSA-1 co-production work involve?**

As part of the ELSA-1 co-production work, you will have an interview with the research team. The interviews will be held in one of two ways, either as an individual interview or as a group, and the study team will advise you of which method you have been assigned to. The interviews will be held mainly by video call, but you can also choose to do phone or an in person interview if you would prefer this.

The video interviews will be held at a convenient time and will last about an hour. The audio will be recorded.

The group interviews will be held as co-production workshops with other professional stakeholders who have been recruited into the ELSA study.



### **5a) What will I be asked in the interview?**

- We will seek your thoughts and ideas about the ELSA testing and monitoring programme for type 1 diabetes, from your perspective as a professional stakeholder.
- We will also seek your thoughts and ideas around the acceptability of families knowing their child is at high risk, from your perspective as a professional stakeholder.
- We will also ask you how best to recruit families into the ELSA-2 study.
- We will ask you what you perceive to be the barriers to participation in a T1D testing and monitoring programme, and how we could overcome them. We will also enquire into how we could widen access to this programme for lower socioeconomic groups.

### **5b) What are the benefits of being part of this study?**

By taking part in this study, you will help us to understand the feasibility and acceptability of a T1D surveillance programme from the perspective of a professional stakeholder. These thoughts and ideas will help us go on to design and modify the testing and monitoring programme in ELSA-2. Also, your insights will help us address and reduce the barriers to a national T1D testing and monitoring programme.

This study has been made COVID-19 friendly and does not put you at any additional risk because there is the option for everything to be done online or by phone. But you have the option to see us in person if you want to. Current government safety guidelines in relation to COVID-19 will be adhered to in all instances.

### **5c) What needs to be considered and what are the risks of taking part?**

The interviews will ask difficult questions about finding children who are at high risk of T1D in the future. However, the interview team are highly sensitive and will ask questions and respond to your answers empathically to reduce any distress caused.

You can choose to stop the interview or withdraw from the study at any time.

### **5d) What if there’s a problem?**

If you have any concerns about the study, you can speak to a member of the research team in the first instance on [elsa@contacts.bham.ac.uk](mailto:elsa@contacts.bham.ac.uk)

If you are unhappy with their response or wish to make a complaint, you can contact the Sponsor’s independent representative Dr Birgit Whitman on [researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)

If you have any concerns about your data or wish to make a complaint about the way your data was handled, you can contact the University of Birmingham’s Data Protection Officer on [Dataprotection@contacts.bham.ac.uk](mailto:Dataprotection@contacts.bham.ac.uk)

## 6) Who can take part in this research?

We are looking to recruit professional stakeholders, including specialist doctors in diabetes care, general practitioners, research doctors, practice nurses, school teachers and school nurses. These individuals have been selected because they are all currently involved in caring for children with T1D and in the future, would be involved in the delivery of a type 1 diabetes testing and monitoring programme.



## Important information

### 7) What will happen to the data from this study and will my data be kept confidential?

Your data will be stored confidentially in line with the Data Protection Act 2018 and General Data Protection Regulations (GDPR).

The audio transcripts from the study interviews, will be transcribed by an external provider, with whom the University of Birmingham has a contractual and data processing agreement in place. Transcripts will be coded after checking the transcription for accuracy. Data analysis will only be performed on coded data, which can only be linked back to your personal data by the study administrator. Only the coded data will be shared with experts in the study team. The data will be published at international scientific meetings and in international scientific journals, but this will all be anonymised.

All participants enrolled on the study will be coded at the time of data analysis. The data will be published at international scientific meetings and in international scientific journals, but this will all be anonymised.

We are using a web design company, Morph, to develop the ELSA study website with whom we have a contractual agreement in place. All data will be handled confidentially, and no identifiable data will be shared with the company.

Postal consent forms will be filed in a secure and locked office.

### **7.1) How we will use information about you?**

We will need to collect information from you for this research project.

This information will include:

- Your initials
- Your name
- Your contact details: mobile number and email
- Age (years)
- Ethnicity
- Gender
- Occupation
- Work address

We will use this information to do the research or to check your data to make sure 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.

### **7.2) What are your choices about how we will use your information?**

You can stop being a part of the study at any time, without giving reason, but we will keep information about you that we already have.

We need to manage your data 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.

### **7.3) Where can you find out more about how your information is used?**

You can find out more about how we use your information:

- On the ELSA website: <https://elsa-study.morphdev.co.uk/privacy-notice-cookie-usage/>
- By asking a member of the research team on [elsa@contacts.bham.ac.uk](mailto:elsa@contacts.bham.ac.uk)
- By sending an email to the University of Birmingham’s Data Protection Officer at [dataprotection@contacts.bham.ac.uk](mailto:dataprotection@contacts.bham.ac.uk)
- By calling us on 0121 371 4407

### **8) Who is leading and funding the study?**

The ELSA-1 study is being led and funded by the University of Birmingham, The Principal Investigators for the study are Dr Parth Narendran and Prof Tim Barrett.

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

Parents and young people are co-applicants on the ELSA-1 research protocol and have also been influential in the design of the study.

### **10) Who has reviewed this study?**

This study is sponsored and insured by the University of Birmingham and has been reviewed and approved by a local and national ethics committee.

### **11) Are there any financial costs to me of taking part?**

No, because the paperwork for this study will all be online and the interviews will be held online or by phone, there will be no cost burden for you. We will also arrange the interviews at a good time for you.

If you prefer to receive and complete the physical paperwork, we will send you the forms and provide pre-paid envelopes for you to return them to us. If you prefer to see us in person for the interviews, we will pay reasonable travel expenses, after your interview and once we have received evidence of your travel.

### **12) Are there any rewards or payments for taking part in this study?**

No, there will be no payments or rewards for being part of this study because there is no cost burden. We are very grateful to the stakeholders who take part in this study and give their time to support our research.

### **13) Further information and contact details:**

Please visit our website for more details about the study. Please see our Frequently Asked Questions section of the website as well.

Please feel free to contact the study team on: [elsa@contacts.bham.ac.uk](mailto:elsa@contacts.bham.ac.uk)

### **14) What happens next if you are willing to take part in the ELSA-1 study?**

1. If you would like to find out more about the ELSA-1 study, please visit our website: [www.elsadiabetes.nhs.uk](http://www.elsadiabetes.nhs.uk)
2. Please let the study team know if you have any further questions.
3. If you are happy to proceed, please email us on [elsa@contacts.bham.ac.uk](mailto:elsa@contacts.bham.ac.uk) and we will send you the online expression of interest and contact details form.
4. Then, the study team will send you the postal consent form with a prepaid envelope for return. A copy of the stakeholder’s consent form can also be found on our study website.
5. We will then send you an online personal details form to complete.
6. Then the study team will be in touch with you to arrange your interview at a convenient time.



**Thank you for taking the time to read this information leaflet.**