



UNIVERSITY OF  
BIRMINGHAM



IRAS ID: 309252

Centre number: \_\_\_\_\_

Participant Identification Number for this trial: \_\_\_\_\_

**Parent/Guardian's consent form**

**Title of Project: The ELSA Study**

**Please initial box**

1. I confirm that I have read the parent/guardian's information sheet or completed the online information tool dated 13.06.2022 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time without giving any reason, without my child's medical care or legal rights being affected. However, I also understand that once analysis has begun, it may not be possible to withdraw mine and my child's anonymised data from the study.
3. I understand that relevant sections of my child's medical notes and data collected during the study, may be looked at by individuals from the University of Birmingham, from regulatory authorities or from the NHS Trust, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records.

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

4. I understand that my personal details including my name, contact details, and demographic details, and my child's personal details, demographic details, medical history and family history will be stored by the researchers for this study.
5. I understand that mine and my child's data will be stored for 10 years after the study completes. A record of mine and my child's personal details will be kept on a secure University of Birmingham server. Mine and my child's paper records will be kept within a secure location in a locked office at the University of Birmingham. Results will be stored in a pseudo-anonymised form. Only lead and co-investigators will have access to this link.
6. I agree to the collection, transfer and storage of my child's samples and/or relevant clinical data (as detailed in the information sheet), for use in this study and for up to 10 years, using a pseudo-anonymised study number. I understand that the samples will be analysed at the University of Birmingham or the Birmingham Children's Hospital.
7. I give permission to be contacted by the study team to be informed of my child's screening test results, by text message, phone call, email and/or letter. I understand that third parties, including Firetext, will be used to send me text messages to inform me of home-testing kit dispatch and my child's antibody results, and DOCmail will be used to send me and my child's GP a letter with my child's screening test results. I agree to my personal data, including mobile phone number and address where relevant to the study, will be shared with these third parties.
8. I give permission for my child's antibody test results to be stored on NHS clinical systems.
9. I give permission for my child to be referred to the local paediatric diabetes service, if my child is found to have a new diagnosis of type 1 diabetes.
10. I agree to take part in the ELSA type 1 diabetes screening programme.

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

**Optional:**

**Yes No**

**Please initial box**

11. I agree that my child's anonymised data and samples may be shared and transferred to other research groups with whom we work in the UK, Europe, and the rest of the world, (including the USA), including industrial partners, for collaborative, ethically approved research studies.
12. I agree to be contacted during the course of the study about collecting additional information to understand acceptability of the ELSA screening programme.
13. If my child is confirmed positive for one or more antibodies from the venous sample, I agree for my child's details to be shared with INNODIA, and I understand INNODIA will feed these results back to the ELSA study team, as detailed in the Participant Information Sheet.
14. I understand that the information held and maintained by the researchers at the University of Birmingham and the NHS organisations involved in this study, may be used to contact me about my child taking part in future ethically approved research or provide information about other studies relevant to my child's screening test results. I give permission for my contact details being used for this purpose.
15. I agree to researchers from the University of Birmingham having access to my child's medical records in order to perform a follow-up study of my child's data at a later date, up to 10 years after the ELSA study.
16. I agree to provide my child's NHS number, for the study team to obtain long-term follow-up data relevant to the study from my child's medical records.

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

ELSA Parent/guardian's consent form

_____	_____	_____
Name of Parent/Guardian	Date	Signature
_____		
Name of Child you are consenting		
_____		
_____	_____	_____
Name of person taking consent	Date	Signature

**Thank you for completing the ELSA study screening programme consent form.**

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

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The ELSA Study