

THE BART'S OXFORD (BOX) FAMILY STUDY: Understanding the causes of type 1 diabetes

Stage 1 Consent Form

One form per family member

for adults (16+yrs) and parents on behalf of children (under 16yrs)

Chief Investigator:	Professor Kathleen Gillespie	Participant identification number:	
Local researcher:		Participant name (in capitals):	
Centre number:			

Please initial each box to show your agreement

PLEASE DO NOT TICK
INITIAL ONLY

1. I confirm that I have read the information sheet dated 06.12.2022 version 2 for the above study. I know what will happen and the possible benefits and risks. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my (or my child's) participation is voluntary and that I/we are free to withdraw at any time without giving any reason and without my (or my child's) medical care or legal rights being affected.

3. I agree for my (or my child's) blood samples to be given for testing and storage, including the extraction and storage of DNA and islet autoantibody testing. I understand that all tests done on my (or my child's) blood or DNA will be relevant to diabetes and related immune research.

4. **THIS QUESTION IS NOT APPLICABLE IF YOU HAVE AN APPOINTMENT WITH A RESEARCH NURSE TO GIVE ONE OR MORE OF THE FOLLOWING SAMPLES.**

Please send me home sample collection kits for the following boxes I have initialled:

- a) A finger prick capillary blood kit (for antibody and T1D biomarker measurement)
- b) A mouth swab collection kit (for the study of type 1 diabetes genes)
- c) A urine collection kit **[ONLY FOR PEOPLE WITH TYPE 1 DIABETES]** (for C-peptide (UCPCR) measurement)

5. I understand that I can choose whether I wish to be given blood test results for islet autoantibody measurement (future risk of developing diabetes) and have understood the potential advantages and disadvantages and had any questions answered satisfactorily. I also understand that I will not be given the results from antibody or genetic measurements carried out on my or my children's DNA.

Islet autoantibody blood test markers:

Yes, I would like to know my (or my child/children's) islet autoantibody markers YES

No, I would not like to know my (or my child/children's) islet autoantibody markers No

Please continue overleaf...

6. I agree that my (or my child's) stored blood, serum, DNA, and urine samples, and the results obtained from testing these samples can be used in diabetes research and related autoimmune and immune conditions that have been approved by the BOX Management Committee and been given independent ethical approval. I understand that my (or my child's) samples and related information will be made anonymous before being used by researchers who are not part of the study team.
7. I understand that any samples I (or my child) give will be coded and made anonymous by the BOX management team before they are sent to national and international research laboratories for additional testing.
8. I understand that there is no set time limit on the duration that my (or my child's) samples can be stored for future diabetes research. They will be kept as long as the Box study has current ethical approval unless I decide that I want my (or my child's) samples to be destroyed.
9. **The following statement is only applicable to the family member who has developed type 1 diabetes: Otherwise, please continue to question 10.**
 I understand that relevant sections of my (or my child's) medical notes may be looked at by a researcher, from regulatory authorities or from the NHS Trust where it is relevant to my (or my child) taking part in this research. I give permission for these individuals to have access to my (or my child's) records.
10. I agree to my (or my child's) GP, and where relevant my (or my child's) diabetes doctor being informed of my (or my child's) participation in the study. (optional).
11. I give my permission that information held and maintained by The Health and Social Care Information Centre and other central UK NHS bodies may be used to help contact me via my (or my child's) general practitioner (GP), in the event that I can't be contacted by the channels I have provided. (optional)
12. I agree (or on behalf of my child) to take part in stage one of this study.
13. I am happy to be contacted about future studies and know that I (or my child) am under no obligation to take part.

Thank you for your help in this study.

Participant signature:
(If aged under 16, a parental signature is required below)

Name (Block Caps):

Date:

Parent signature:

Name (Block Caps):

Date:

For office use:

Name of person taking consent signature:

Name (Block Caps):

Date: