

STUDY NAME: EXE-T1D

Understanding beta-cell destruction through the study of **EX**tremely **E**arly-onset Type 1 diabetes

Version: 1.0 01.03.2022

CI: Professor Richard Oram

[PI: XX]

Participant ID:

Parent/Guardian of Child Control Participants CORE CONSENT STATEMENTS		Please circle answer	Please initial
I have been given the study information leaflet (Version 1, 01.03.2022). I have had the opportunity to ask questions and have had these answered satisfactorily.		YES / NO	
I agree for my child to: <ul style="list-style-type: none"> • have an appointment(s) as detailed in the study flowchart. • provide information about their health for use in this project. • allow the research team to contact my child's clinicians/GP about their treatment and study participation now and in the future. • provide blood samples for analysis, including genetic studies using DNA. Samples will be stored for the duration of the study. 		YES / NO	
I understand that: <ul style="list-style-type: none"> • my child's participation is voluntary and that they may withdraw at any time without their clinical care being affected. • individuals from the study team, regulatory authorities or the UK NHS Trust will have access to relevant sections of my child's medical notes and data collected during the study for research, monitoring and audit purposes. • the research data and samples will be stored separately and securely from any identifiable data, by using an ID format to protect my child's confidentiality. • my child's clinical samples will be sent for testing at the Exeter Clinical Laboratories, together with three forms of identifiable information (name, DOB, NHS/CHI/hospital number) in accordance with the NHS requirements for clinical sample analysis. The clinical results will be made available to my child's clinician and/or GP, if they might help with their ongoing medical management. 		YES / NO	
I agree for my child to take part in this research study.		YES / NO	
OPTIONAL CONSENT STATEMENTS			
I agree for my child to gift samples and data from the project to the Peninsula Research Bank, managed by the NIHR Exeter Clinical Research Facility, to be used for future research with ethical approval.		YES / NO	
I agree that information held by the Exeter Molecular Genetics Laboratory and in my child's medical records may be used to follow up on my child's future health status.		YES / NO	
I am happy to be contacted by the research team about participating in other future studies.		YES / NO	
PARTICIPANT NAME (PRINT)		DATE	
PARENT/GUARDIAN NAME (PRINT)	SIGNED		
RESEARCHER / CLINICIAN			
I confirm that I have obtained valid informed consent from the above patient's parent/guardian.			
NAME (PRINT)	SIGNED	DATE	

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