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Site logo

CI: Professor Richard Oram
[PI: XX]

STUDY NAME: **EXE-T1D**

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

Version: 6 24.11.2022

Participant ID:

| **Adult Participants**<br>**CORE CONSENT STATEMENTS** | **Please circle answer** | **Please initial** |
|---|---|---|
| I have been given the study information leaflet (Version 6, 24.11.2022). I have had the opportunity to ask questions and have had these answered satisfactorily. | YES / NO | |
| I agree to:<br>• have an appointment(s) as detailed in the study flow chart in the information leaflet.<br>• provide information about my health for use in this project.<br>• allow the research team to contact my clinicians/GP about my treatment and study participation now and in the future, and to provide them with clinical results relevant to my care.<br>• provide blood and/or urine samples for analysis, including genetic studies using DNA. Samples will be stored for the duration of the study. | YES / NO | |
| I understand that:<br>• my participation is voluntary and that I may withdraw at any time without my clinical care being affected.<br>• individuals from the study team, regulatory authorities or the UK NHS Trust will have access to relevant sections of my medical notes and data collected during the study for research, monitoring and audit purposes.<br>• the research data and samples will be stored separately and securely from any identifiable data, by using an ID format to protect my confidentiality.<br>• my 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 clinician and/or GP, as they may help with my ongoing medical management. | YES / NO | |
| I agree to take part in this research study. | YES / NO | |
| **OPTIONAL CONSENT STATEMENTS** | | |
| I agree 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 medical records may be used to follow up on my 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** | |
| **SIGNED** | | |
| **RESEARCHER / CLINICIAN**<br>I confirm that I have obtained valid informed consent from the above person. | | |
| **NAME (PRINT)** / **SIGNED** | **DATE** | |

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