Please note: this is a sample consent form and for your information only. You do not need to complete this form or print it out. Informed consent will be taken over the telephone. It is a two-way conversation between you and the researcher.

University of Southampton

CONSENT FORM

Study title: ***The REFLEX study*** - Reflex testing for metabolic associated fatty liver disease (MAFLD) in patients living with type 2 diabetes compared to usual care - a randomised controlled trial

ERGO ID: 80205 **IRAS ID:** 326212 **Chief Investigator**: Professor Christopher Byrne

Participant Identification Number*:* _____

1	I have read and understood the information sheet (PIS_V3.5.1, 14/7/23) and have had the opportunity to ask questions about the study.	
2	I agree to take part in this research project and understand that I will be randomised to one of two groups. Group A or B.	
3	I consent to have a liver assessment using the FibroScan device and provide a blood sample.	
4	If randomised to Group B: (i) I understand that I will be offered my Fibroscan approximately 12 months after today (date of consent). I give permission for the research team to contact me to organise the liver assessment. (ii) I understand that the research team will need access my GP records over the next 12 months.	
5	I consent for my blood sample to be stored at the University of Southampton for the duration of this study	
5a	At the end of the study, I consent/do not consent for my left-over blood to be sent for archive storage at the Southampton Faculty of Medicine Tissue Bank (Human Tissue Authority Licence No: 12009) for use in future ethically approved health related studies.	
6	I understand that that all my details will be kept confidential, my name will not appear on any documents and I will not be directly identified in any reports of the research.	
7	I consent for the research team to access my patient records to obtain health data relevant to this study and for my data to be used for the purpose of this study .	
7a	I consent/do not consent for the research team to access my patients records to obtain health data for the next 10 years where it is relevant for research.	
8	I understand that where it is relevant to my taking part in this research, sections of my medical notes and data collected during the study may be looked at by the research team, regulatory authorities, the research sponsor or the NHS Trust. I give permission for these individuals to have access to my records.	
9	I understand that the results of my liver assessment will be overseen and monitored by clinicians at University Hospital Southampton who may need to contact me or refer me directly to liver health services that are local to me	
10	I consent for you to inform my GP of my liver assessment results.	
11	I understand my participation is voluntary and I may withdraw at any time for any reason without my participation rights, medical care or legal rights being affected.	
12	I would/would not be interested in receiving information about any future relevant liver studies (delete as appropriate). Please contact me via email/text/telephone/post (delete as appropriate) on: _____ _____	

Name of participant (print name): …… Date: ……

Signature of participant: ……

Name of researcher (print name) …… Date: ……

Signature of researcher ……