UNIVERSITY OF PLYMOUTH

NHS University Hospitals Plymouth NHS Trust

Patient participant Consent Form

Title of study:
The role of an implantable Doppler vascular monitoring device in kidney transplant patients: a feasibility randomised controlled trial with an embedded qualitative study.

Principal Investigator: Dr M Shahzar Malik

Participant Identification Number for trial:

Please initial each statement as appropriate	
1. I confirm that I have read the patient participant information sheet (PPIS v1.1 (final); 04 Feb 2022) for the study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected, however, any data collected up to the point I withdraw may still be used in the study analysis.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University Hospitals Plymouth NHS Trust, or Regulatory Authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I understand that if I agree to participate in future research, the information collected about me in this study may be used to support other research in the future and may be shared anonymously with other researchers.	
5. I understand that my data including direct quotes obtained from me during the interviews may be used internally in a dissertation or published externally in presentations or journal articles. However, my data would be anonymous, and it will not be possible to identify me either directly or indirectly in publicly disseminated reports or published study in medical journals.	
6. I understand that my privacy and confidentiality will be maintained at all stages of the study under the provisions of the Data Protection Act 2018.	

7. I understand that at the end of the study my data will be securely archived for 10 years before arrangements for confidential destruction will be made, in line with Trust policy.	
8. I understand that my interview will be audio recorded to gather all relevant information and it will be deleted immediately after transcription.	
9. I understand that if I'm allocated to receive the vascular monitoring device, I may be approached on the day of its removal to take part in a semi-structured interview to discuss my views however, I am able to decline if I wish.	
10. The study procedures have been explained to me along with the potential benefits and risks. I have had the opportunity to ask questions.	
11. I agree to take part in the above study.	

This is optional - please initial either Yes or No for each statement	**YES**	**NO**
11. I agree to my personal information being stored confidentially by the research team so that they can contact me with details of future research projects and that there will be no obligation for me to participate		

Consent Signatures

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person receiving Consent	Date	Signature
Time of Consent (24hr clock)	_____ : _____	

1 copy for participant; 1 copy in medical notes and 1 copy for researcher site file.